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August 21, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5522-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program; CY 2018 Updates to the Quality Payment Program

Dear Ms. Verma:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to **Medicare Program; CY 2018 Updates to the Quality Payment Program** published in the Federal Register on June 30, 2017. The ACS was founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice.

OVERVIEW

The ACS thanks Centers for Medicare & Medicaid Services (CMS) for continued flexibility in the second year of MIPS, and we greatly appreciate the opportunities we have had to partner with CMS to help implement the complicated statutory requirements of Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). **The congressional intention for the Quality Payment Program (QPP) is to integrate and streamline the existing CMS quality programs to reduce administrative burden, improve payment accuracy, and ensure that measures are meaningful to patients, providers, and other stakeholders.** MACRA also recognizes the importance of working closely with physician stakeholders to create a strong, clinically sound program with buy-in from providers.

ACS is dedicated to the congressional intent of MACRA and supports incentives in the QPP to transition from the Merit-based Incentive Payment System (MIPS) to Alternative Payment Models (APMs) promptly. However, we encourage the Agency to provide a clear path toward quality and value to help achieve the intent of MACRA. Based on the proposed rule, the MIPS program does not enable the ability to reliably and validly compare physicians within and across specialties. And, the MIPS program has taken the past CMS



legacy programs and made them more confusing for providers to figure out and participate in.

In our comment letter, we highlight the following high-level issues that we believe will work to achieve the intent of MACRA:

1. **Clarify the Agency's Goal for the QPP Program.** We seek clarity and direction from the Agency on the goals of the QPP. ACS believes, at a minimum, physicians should report care based on common conditions with common measures which works toward the goal to have a single source of truth (one system to aggregate data for MIPS) for accurate and reliable quality measurement and improvement. This goal cannot be achieved with the proposed multiple disparate data systems which have competing measures and methodologies.
2. **Increase Benchmarking Reliability and Validity.** The current CMS solutions to measurement science are inadequate for accurately informing patients and providers. We need solutions that provide consistent reliable methods, including: standardized data definitions, standardized risk adjustment/data analytics, consistency of data ascertainment methods, and common normalization methods.
3. **Amend Quality Performance Period.** Modify the quality performance year to align with 90-day reporting for Advancing Care Information (ACI) Performance Category and Improvement Activities (IA) Performance Category.
4. **Further Investment in Research for Socioeconomic Status Risk Adjustment.** CMS proposes a bonus for providers with complex patients while seeking feedback on which social risk factors to include in risk adjustment or the stratification of risk factors. These proposals fall short on the promise to provide reliable and valid risk-adjusted measurement. We encourage CMS to work with other Department of Health and Human Services (HHS) agencies to further prioritize research efforts to examine the broader social determinants of health.
5. **Meaningful Measures That Incentivize Episode-based Care with Shared Accountability.** Measures proposed for each MIPS category (Quality, Cost, ACI, IA) have been created in siloes and do not align with the care provided across clinical practice. Current quality measures are singleton not meaningful; episode-based cost measures are not tied to complementary quality measures; IA activities do not align with quality measures to portray a cycle of improvement. The

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MIPS program should begin with a framework similar to the ACS guiding principles of quality improvement: setting clinical standards, building the right infrastructure, using the right data, and verifying with outside experts. Next, these data can serve as a source of trusted information upon which to measure and improve. For surgery, quality measures, IA, and cost episodes should align and follow the five phases of surgical care—preoperative, perioperative, intraoperative, postoperative, and post-discharge for a comprehensive and meaningful cycle of improvement.

6. **Topped Out Measures.** ACS opposes the general removal of all measures based on topped out status but supports a modified proposal that would provide an option to transition high value topped out measures into a composite.
7. **Promote Widespread Interoperability.** The objective of ACI should be the attainment of widespread health data interoperability, not only between meaningful users of certified EHR technology (CEHRT), but more broadly throughout the wider clinical data ecosystem. Clinical data require open source interfaces, open source reference architectures for clouds and apps in order provide analyzed information in a usable format.
8. **Enhance the Utility of Virtual Groups.** Virtual Groups should be seen not only as an alternative reporting option but as a tool in helping small practices and solo providers to succeed in MIPS and transition to APMs and Advanced APMs. To achieve this, CMS should maintain flexibility in the Virtual Group option, including allowing for third-party participation in virtual group agreements.
9. **Recognize MIPS APMs as a step in the continuum from MIPS to Advanced APMs.** CMS should make it as accessible as possible for physicians to transition from MIPS, to MIPS APMs, to Advanced APMs. Considering MIPS APMs as a stepping stone between MIPS and Advanced APMs is one way to create an incentive for physicians to move toward Advanced APMs, which is one of the clear goals of MACRA. We urge CMS to view MIPS APMs as a lower risk option for physicians to test out APM participation.
10. **Align Advanced APM requirements and maintain flexibility.** We support alignment between the Advanced APM Medicare Option and the All-Payer Combination Option with respect to the criteria for determination and other requirements for the two options. This will

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allow payment models to be more easily implemented across payers. We also urge that CMS maintain flexibility when applying the Advanced APM criteria because not all APM structures are the same and the criteria should remain adaptable to allow for innovation in meeting the stated goals of MACRA.

QPP GENERAL COMMENTS: SEEKING A CLEAR PATH TOWARD QUALITY AND VALUE

As discussed, the current MIPS proposals increase program complexity through multiple disparate data systems with competing measures and methodologies. We understand that it is difficult to achieve a reduction in the burden for program compliance with simultaneously compounding complexity required by statute—all while hoping to maintain reliability and validity. We also recognize that it is challenging to create regulations that ultimately lead to better care and not simply better compliance with the rules.

However, as proposed, we believe the program will suffer harsh criticism for its lack of rigor. For the 2018 performance year, CMS has proposed new flexibilities and opportunities to gain additional points to try to balance the complexities of the QPP. While we appreciate the efforts behind these proposals, the flexibilities proposed in the short term will result in a provider's performance being judged inaccurately in the long term due to a lack of data integrity. We seek clarity from CMS on its short and long-term goals for the QPP:

- ***In the early years of QPP, is CMS' goal to recruit physicians into the program, regardless of its overall accuracy?*** Without measurement rigor, CMS will recruit physicians into an inaccurate measurement system which will lack a reasonable and meaningful ability to co-aggregate information from unrelated data sources. This will lead to overly complex normalization and analytic failures which will misclassify physicians, making senseless comparisons across physicians.
- ***Or is the goal to be able to compare physicians within and across specialties with reliability and validity?*** In this instance, early efforts should be focused on CMS seeking advice on how best to create measurement rigor which provides a trusted source for data elements, consistent and reliable aggregation, normalization and analytics which suit the measure purpose and timely reports to those charged with accountability and improvement.
- ***Is the longer-term goal to define value in the care physicians deliver and create payment models based on care? Or is the goal to exclude***

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the majority of physicians and only define value in large groups? If value-based health care is pursued, creating a foundation based on solid measurement principles will avoid the cleanup that will be needed if CMS initially pursues less rigorous and inaccurate methods.

If CMS' general goal is to define value with reliable and valid quality and improvement, at a minimum CMS should work toward the goal of having physicians report care based on common conditions with common measures into a single source to allow for standardized data analytics. More ideally, these measures should be patient-centered and have shared accountability for all clinicians who provide for an episode of care—and fit the bill for common conditions, common measures in a single source of truth. ACS also believes the QPP program should work to better support providers and incentivize optimal care while prioritizing a reduction in regulatory burden. **If CMS is committed to the MACRA goal of creating incentives to move from MIPS to APMs, CMS should provide a roadmap that outlines how the regulations incentivize quality clinical care while designing business models that promote the successful transition from fee-for-service payment updates to new clinical and financial models of care.** To help facilitate this effort, ACS outlines a framework for short, medium, and long-term goals for QPP success in surgery.

ACS VISION:

Short-Term

For the short term, it is critical to increase reliability and validity in the current quality and cost measures. In general, measurement science has done well in establishing measure specifications for defining the numerators, denominators, and the inclusion/exclusion criteria. However, building those measures into a meaningful metric requires more than scientific specifications. **Measures must be consistently aggregated, normalized, analyzed and represented with great rigor to provide value. Without any one step in the measurement process, the result will include serious errors and untrusted measurement.**

The ACS illustrated these points when we harmonized the ACS National Surgical Quality Improvement Program (NSQIP) surgical site infection (SSI) measure with the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) SSI measure based on information available using the harmonized measure specifications in the **same** facilities. After harmonization of measure specifications (i.e. common data elements), results showed that NSQIP participants had higher SSI rates compared to the CDC NHSN registry. Through further study, ACS found that this discrepancy

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was not because NSQIP participants had poorer surgical outcomes, instead, the discrepancy was due to the lack of rigor used to track patients and collect data for use in the NHSN registry when compared to NSQIP.¹ **In the short-term, the MIPS measurement system needs rigor in common data aggregation, common data analytics, and reporting.** The Society for Thoracic Surgery (STS) National Database is an example of consistency and validity across measurement because one data system exists for a small number of operations, allowing for a single method for data aggregation, analytics, and reporting. If STS had multiple vendors collecting, normalizing, and analyzing data under differing rules and logic, results would not be as useful even after large expansive effort. We encourage CMS' short-term efforts to move toward solutions that provide a single source of truth for all measurement science elements with inputs from appropriate experts. It is important to also highlight that CMS must consider how to best provide outcome measures that discern quality of care with reliable confidence for patients and for payment accountability.

Medium-Term

The medium-term goal seeks to move away from fragmented, singleton measures which do little to support quality, improvement, and true accountability. The current measures only depict a “moment in time,” resulting in scattered pieces of information across a physician practice, while never representing the picture of care a patient receives across the care continuum. ACS believes the solution is the development of a measure framework inclusive of high value process measures across an episode of care coupled with complementary patient reported outcome (PRO) and patient reported experience (PRE) measures. We believe measuring a patient's care across the phases of surgical care aligns with a patient's clinical goals. To this end, ACS believes CMS should explore patient-centered measures that evaluate patient outcomes and the individual contributions attributed to the team-based episode of care with shared accountability. This framework will build on the reliable and valid measurement science discussed above as part of the short-term goal while creating a path toward participation in an APM. Models should be developed which reward surgical team members for team-based measures in MIPS and promote these measure models for use in APMs.

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¹ Ju, M. H., Ko, C. Y., Hall, B. L., Bosk, C. L., Bilimoria, K. Y., & Wick, E. C. (2015). A comparison of 2 surgical site infection monitoring systems. *JAMA surgery*, 150(1), 51-57.



Long-Term

The long-term goal involves appreciating three interrelated aspects of care:

- First is the achievement of team-based, episodes of care in modern clinical care models for all diseases and conditions.
- Second, these care models call for an interoperating digital health information infrastructure which serves to inform care and automate measurement.
- Third, business operations and payment systems must align with clinical care models.

The care model relies on the key roles each clinician provides at the right time. This includes primary care, which forms the home (or hub) of activity and as acts as the interface between clinical teams. Clinical teams provide care across the care spectrum (preventive and screening services, simplistic acute clinical conditions, complex acute care, chronic care, rehab, and end of life). It is critical that *all* the providers who contribute to care must be supported in the digital health infrastructure to allow data to flow between providers who treat a given patient. ACS believes the reliance on longitudinally-tracked episode-based quality measures, high-value process measures, and PROs (discussed above) are ideal for this long-term vision. Patient-centered measures should have shared accountability for all the care team members. When patients' goals are met, providers are rewarded. This vision is illustrated in Appendix A which provides a cancer care model example.

To achieve this, CMS must realize that the complexity of modern medicine has exceeded the ability of a single physician to provide all the care a patient requires because there are limits to the amount of information one can process.² Below, Figure 2 illustrates just how complex a care environment can be. The picture of an infant in the NICU shows there are often hundreds of parameters needed to monitor and treat a patient. In an environment with hundreds of parameters, providers are also bombarded with interruptions and distractions which is a formula for overload and failure. Longitudinally mapping patients' needs when they suffer from multiple chronic diseases and acute exacerbations is equally complex. Medical errors are the third leading cause of death in the U. S.—it is estimated that 250,000 people die each year in the US as a result of a medical error.³ Many of these errors can likely be

² McDonald, C. J. (1977). LIMITATIONS. *Pediatrics*, 59(3), 456-456.

³ Makary, M. A., & Daniel, M. (2016). Medical error—the third leading cause of death in the US. *BMJ: British Medical Journal (Online)*, 353.

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prevented if providers are given data to inform care and thereby prevent the error. Physicians, nurses, and other members of the care team need machine readable and analyzed information represented to them in a useful format.



Figure 2: How Can ICU Clinicians Manage the Data from All These Monitors⁴

To support this vision, ACS believes CMS and all related government agencies should work together to seek to promote interoperability in the ACI program. Such interoperability is consistent with the longitudinal, coordinated care models promoted in the QPP program and would reduce patient and physician frustration. However, we must build this based on coordinated care model because fee-for-service payment models inherently promote silos of care. If care remains siloed we cannot successfully track patient success longitudinally,

⁴ Howe, Scott. How Can ICU Clinicians Manage the Data from All These Monitors? Digital image. Vector Boston Children's Hospital's Science and Clinical Innovation Blog. Boston Children's Hospital, 14 Mar. 2014. Web. 1 Aug. 2017.
<<https://vector.childrenshospital.org/2013/03/raising-an-early-warning-in-the-icu-t3/>>.



and current information barriers, including data blocking, will continue. To these points, ACS asserts that it is impossible to give the safest, best care in medicine without improved data integrity, reduced burden of data aggregation, and the promotion of larger data exchanges. CMS must focus its measurement needs within this entire clinical and data environment.

ACS Efforts to Support QPP Implementation

In anticipating the intent of MACRA, ACS has made huge investments with an expedited timeline to support surgeons and other providers to provide a path toward success in MIPS and APMs. The surgical roadmap as we see it includes the following projects and ACS commitments:

- We have developed an APM to serve surgical patients and all physicians attributed to the condition or procedure tied to the episode of a surgical disease. The ACS APM proposal includes 54 episodes as a starter set. Full deployment would require inputs from other specialties with CMS to allow for the more than 1200 episodes to undergo testing. We anticipate that this model will also qualify as an Advanced APM for purposes of the MACRA APM incentive payment.⁵
- ACS is developing a comprehensive measure framework inclusive of high value process measures across an episode of care coupled with complementary patient reported outcome (PRO) and patient reported experience (PRE) measures to measure surgeons across the phases of surgical care. This will help providers transition smoothly from MIPS to APMs.
- We are currently working with Health Level Seven International (HL7) and the Health Services Platform Consortium (HSPC) to complete a framework for terminology standards and value set bindings for cancer interoperability to illustrate the vision and a set of clinical domains with semantic and process interoperability. This activity is in partnership with the Commission on Cancer, the Veterans Health Administration (VA), HL7 and the digital health information technological community such as the Healthcare Information and Management Systems Society (HIMSS).
- We are developing a single platform for our clinical registries with common clinical data elements and automated workflows. The ACS intention is to automate data flows through Application Programming Interfaces (APIs) and to support the transition toward episode-based care with shared accountability. This requires the seamless flow

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⁵ Proposal for a Physician-Focused Payment Model: ACS-Brandeis Advanced Alternative Payment Model [PDF]. (2016, December 31).



(multidirectional) of complex digital information from multiple data sources for a patient, regardless of their site of care.

CMS PROPOSALS

MIPS Program Details

MIPS ELIGIBLE CLINICIANS

Small Practices

ACS acknowledges the need to determine in advance which practices qualify as small is legitimate based on the impact such determination has upon eligibility for technical assistance, applicable IA criteria, the hardship exception for the ACI performance category, and the small practice bonus. While there is obviously no perfect process, **ACS is comfortable with the proposal whereby group size determinations are based on the number of NPIs associated with a TIN.**

EXCLUSIONS

Low-Volume Threshold

The ACS greatly appreciates CMS' proposal to alter the low volume threshold and is in firm agreement with CMS that the proposed changes will serve to reduce the burden on small and rural practices. The ACS commends CMS for taking time to carefully analyze data and make changes to the low volume threshold that, while serving to diminish administrative burden on 134,000 providers, also includes the significant majority of Medicare payments. It is our sincere hope that going forward, the threshold will be maintained at numbers no lower than that proposed for the 2018 performance period so that providers may have certainty of the criteria and their participation responsibilities from year to year.

The ACS is also in strong agreement with the proposed changes in the methodology and data analysis in determining which MIPS eligible clinicians and groups are excluded from MIPS via the low volume threshold. Specifically, any changes, such the use of a 30-day claims runout, that allow CMS to complete its analysis earlier and provide determinations in a timelier manner are most welcome. Because of the delay in notification this year, many of our Fellows questioned well into the 2017 performance period, (late April – early May), whether they would be excluded from MIPS. Anything CMS can do to ensure more timely notification prior to the 2018

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performance period without compromising data collection will be greatly appreciated.

About CMS' request for comment on its proposal to allow those who meet only one of the low volume threshold determinations to opt-in, **ACS has no specific objections and applauds CMS for making multiple options available to providers.**

GROUP REPORTING

CMS notes that that provider groups have asked to allow a portion of a group to report as a separate subgroup on measures and activities that are more applicable to them and that their MIPS score be based on the performance of the subgroup. CMS explains that they are exploring the feasibility of this request, including allowing this functionality through a new MIPS identifier.

ACS supports flexibility which would allow for providers to report measures that they find meaningful and have been shown to drive improvement in care. We have heard from many surgeons that their institution or employer currently reports via the CMS Web Interface which does not include measures meaningful to surgical care. **Therefore, we believe this would allow specialists who form subgroups to better utilize more meaningful robust measures, such as QCDR measures, for targeted quality improvement.** As CMS considers the implementation of this policy, we encourage CMS to see how sub-group reporting can promote team-based care with shared accountability, how this could help providers transition to an Advanced APM, and how to provide this option without increased reporting burden on groups.

VIRTUAL GROUPS

CMS solicits public comment on proposals related to Virtual Groups, as well as its approach of not establishing classifications (e.g. classification by geographic area or specialty) regarding Virtual Group composition, or a limit on the number of TINs that may form a Virtual Group.

The ACS believes that the MIPS Virtual Group option has the potential to more meaningfully align measurement based on care delivery models. **Therefore, ACS supports the CMS proposals related to Virtual Groups and agree that CMS should not establish limitations on forming a Virtual Group by specialty or geographic area.**

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We strongly encourage CMS to maintain this flexibility in future years to reduce administrative burden and address some of the barriers to participation faced by solo practitioners and small practices, particularly, but not limited to, those in rural areas. We thank CMS for proposing a flexible two stage Virtual Group election process and for making the first stage optional. This will allow providers and practices unsure of their eligibility to determine this while not placing an unnecessary requirement on practices who feel comfortable participating without this extra level of guidance.

Application of MIPS Group Policies to Virtual Groups

CMS proposes to apply MIPS group policies to Virtual Groups except as otherwise specified. CMS is also interested in feedback on how such group-related policies previously established and proposed in this proposed rule either would or would not apply to Virtual Groups.

The ACS believes that CMS' proposal to assess Virtual Groups across all four MIPS performance categories at the group level is reasonable and agrees that requiring Virtual Group participants to report both as a group and separately could be burdensome.

We are, however, concerned that the benefits of forming a Virtual Group could be outweighed for some by the loss of the proposed bonus points for small practices that will occur if the virtual group includes more than 15 individuals. While the virtual group option as proposed mirrors the group reporting option, each TIN in the virtual group will by definition include 10 or fewer individuals, well within the definition of a small practice set forth in MACRA. It is important to recognize that simply aggregating data from multiple small practices for reporting purposes is not equivalent to the resources and care coordination benefits possible in large integrated group practices. In addition, given that CMS has the authority to create additional MIPS identifiers as needed (and is considering doing so to allow for subgroups inside of TINs to organize differently for MIPS reporting), we believe that the congressional intent of limiting the Virtual Group concept to groups of 10 or smaller was precisely to provide a benefit to small groups. To remove the small group policies from those small practices that combine to form Virtual Groups larger than 15 individuals would undermine that benefit.

If CMS decides to phase out the small practice bonus points for Virtual Groups of a certain size, this threshold should be set at a much higher number so as not to dissuade practices from joining together in the first place and to recognize the fact that the constituent TINs within the Virtual Group remain small practices without the advantages enjoyed by large integrated groups. This will

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likely be especially true for many solo practitioners and small practices who only slightly exceed the low volume threshold or who choose to opt-in. These practices will likely have the greatest challenges and most difficulty succeeding in the program.

Virtual Group Agreements

The ACS feels that Virtual Groups should be authorized to partner with third-party data aggregators, providers of advanced data analytics, and other service providers who can help leverage economies of scale to reduce barriers to successful participation for small practices and solo practitioners.

In the 2015 MACRA RFI (42 CFR Part 414 [CMS-3321-NC2]), CMS requested feedback related to who should have access to feedback reports stating: “Should other entities be able to access the feedback reports, such as an organization providing MIPS-focused technical assistance, another provider participating in the same virtual group, or a third-party data intermediary who submits data to CMS on behalf of the provider, group practice, or virtual group?” This indicates that at the time CMS had envisioned a role for third-party intermediaries. However, the current proposed rule indicates that the Virtual Group agreement may only be between participating TINs and explicitly states that: “*the agreement may not be between a virtual group and another entity, such as an independent practice association (IPA) or management company that in turn has an agreement with one or more TINs within the virtual group.*”

The ACS seeks clarification as to if this language is intended only to meet the statutory requirement in MACRA that the formal written agreements be “among MIPS eligible professionals electing to be a Virtual Group” or if it is the intent of CMS to prohibit arrangements between Virtual Groups and third parties for data analytics, aggregation and reporting, and other services that could improve care coordination and outcomes. If the latter, we strongly urge CMS to reconsider this position as it would greatly reduce the utility of the Virtual Group option to enhancing outcomes and goals such as coordination of care.

The ACS argues that ideally there should be a clear continuum of participation in the QPP, starting in traditional fee-for-service Medicare in the MIPS program and progressing to early participation in MIPS APMs, and ultimately, voluntary participation in an Advanced APM. If implemented correctly, the Virtual Group option could be an important tool in achieving this goal while simultaneously furthering the stated CMS goal of enhancing health outcomes and improving care coordination. To accomplish this most efficiently, it will

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be beneficial to allow for third-party intermediaries to contract with these small practices and solo practitioners (as mentioned previously). This will allow these practices to benefit from resources, (such as advanced data analytics) greater than those available to most individual small practices.

For some, participation in a Virtual Group could be the first step in working across specialties in efforts to improve care coordination that could ultimately lead to participation in an APM or A-APM entity. For this reason, we believe the proposal to include all members of a Tax Identification Number (TIN) in the Virtual Group but apply the APM scoring standard to those eligible clinicians participating in APM entities is reasonable.

MIPS PERFORMANCE PERIOD

CMS explains that in the CY 2017 QPP Final Rule the Agency finalized that the 2020 QPP payment period would have a 12-month performance period (January 1, 2018 through December 31, 2018) for the MIPS Quality and Cost performance categories. The IA and ACI performance categories would continue to have a 90-day reporting minimum. CMS does not propose any changes to these categories for the 2018 performance year.

While we appreciate that CMS finalized these policies last year which will allow providers and vendors additional time to prepare for the increased 12-month reporting period, **we strongly urge CMS to allow for a minimum of 90 days of reporting the Quality performance category.** CMS could offer additional points for providers who report beyond 90 days, such as 6 months, 9 months, or 12 months. Challenges in the 2017 performance year have demonstrated that we simply do not have the systems in place to support a 12-month performance period for the Quality component. Some examples include:

- **CMS did not approve ACS QCDR measures until July 2017 and CMS required major changes to the submitted measures just days before approval, resulting in delayed registry launch dates.** As a result of the late approval and major changes, ACS will not be able to launch our QCDR measures until September 2017, which will give providers less than four months to enter data for 2017. The likely result is that most surgeons will not choose to report QCDR measures given the burden of retrospective data entry as well as the fact that they have not have time to familiarize themselves with the new measures.
- **Most registries require manual data entry and therefore do not have seamless data transfer from EHRs or other data sources.** Due to the lack of interoperability in the current clinical care system, 50% of

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all-payer data for a 12-month period is too burdensome for the early years of MIPS.

- **CMS delays in 2017 demonstrate that a January 1, 2018 start date is not feasible for providers.** Given the delays in sub-regulatory guidance, the delayed announcement of MIPS eligibility, the delay in the Eligible Measures Applicability (EMA) process, and the short time period before the finalization of the QPP rule there is simply not enough time for providers to prepare for a January 1, 2018 start date for reporting the Quality performance category.

Furthermore, for stability and simplicity, the ACI, IA and Quality performance categories should be aligned in their reporting period of 90 days for the early years of MIPS. Providers are still in the process of understanding the basics of MIPS, and how to participate. Many of our members have told us that they plan to “test” MIPS participation in 2017, which means that 2018 will be their first year of true MIPS participation. CMS must keep the MIPS program consistent and approachable to engage providers.

MIPS PERFORMANCE CATEGORY AND MEASURES ACTIVITIES

Performance Category Measures and Reporting

Submission Mechanisms

ACS does not support CMS’ proposal to allow providers and groups to submit data via multiple submission mechanisms. Beginning in 2018, CMS proposes to allow MIPS providers and groups to submit data on measures and activities via multiple submission mechanisms for a single performance category. CMS explains that for MIPS providers and groups that have fewer than the required number of measures and activities applicable and available under one submission mechanism, in order to receive the maximum number of points under a performance category, they could be required to submit data on additional measures and activities via one or more additional submission mechanisms, as necessary, provided that such measures and activities are applicable to them.

While we appreciate CMS’ response to certain stakeholders who requested this change in policy, **we do not support this proposal because ACS believes that allowing for multiple submission mechanisms is unnecessarily overcomplicating the MIPS program while also adding to provider burden.** Our main concern is that this policy will now require a provider to identify six MIPS measures across all reporting mechanisms—QCDR, claims, EHR, and registry, rather than just review one source of measures and one way

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to report. The primary objective of this proposal appears to be compliance with payment program requirements that are not tethered to measuring key elements of a practice's quality or focus areas for improvement.

This also leads to confusion regarding how measures will be reviewed via the eligible measure applicability (EMA) process—the process that replaces the previous measure applicability validation (MAV) process. We understand that the EMA process will only apply to claims and registry measures and that providers who choose EHR measures or QCDR measures must identify at least six measures or will not be eligible for the full quality score unless they find additional measures via other submission mechanisms. However, we believe this new policy will require MIPS providers to search through both claims and registry measure lists (at a minimum) to identify measures instead of reviewing just one submission list or simply choosing the measures in the traditional MIPS registry they have used in the past. This will be especially difficult for providers who have traditionally reported through either registry or claims—not only will they have to review more measures—the provider or their office manager will have to employ a new mechanism to report, adding to reporting burden. We seek clarification on these concerns and urge CMS to publish the EMA sub-regulatory guidance. It is difficult to provide concise feedback on these proposals without know how the EMA process will impact providers. **As proposed, we do not support the ability to report via multiple submission mechanisms for a single performance category.**

Quality Performance Criteria

Contribution to Final Score

CMS proposes to reweight the quality performance weight to 60 percent to account for CMS' proposal to weight the Cost performance category at 0 percent for the second MIPS payment year (2020). **ACS strongly supports the quality performance weight of 60 percent for the 2020 payment year.** As discussed in the Cost category, we strongly support the weight of 0 percent for the 2020 payment year, and believe that the additional 10 percent should be distributed to Quality. Many providers are more familiar with the Quality performance category and this will also allow for consistency, stability, and simplicity for the second year of MIPS.

Quality Data Submission Criteria

SUBMISSION CRITERIA

Although it is not a requirement to report cross-cutting measures, CMS

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proposes a list of cross-cutting measures to provide a reference to clinicians who are looking for additional measures to report outside of their specialty. **ACS agrees that cross-cutting measures should not be a mandatory reporting requirement. If CMS wishes to encourage reporting cross cutting measures, the Agency could consider classifying them as high priority measures.** In addition, we question whether there is any data that demonstrates cross-cutting measures drive improvements in care—we do not know of any evidence that cross-cutting measures have done so in surgery.

Instead, we ask CMS to consider what types of measures would be appropriate for measuring all members who are part of a given episode of care with shared accountability. **ACS believes the key concept in identify cross cutting measures is measuring providers or specialties who have a patient(s) in common—what does not work for cross-cutting comparisons is measuring providers when they do not share care for a specific patient.**

DATA COMPLETENESS CRITERIA

CMS explains that the Agency is concerned about accelerating the data completeness threshold too quickly. Therefore, CMS proposes to maintain the current (2017) data completeness thresholds for the 2018 performance year:

- Traditional MIPS Registry: 50% of all applicable patients, regardless of payer
- QCDR: 50% of all applicable patients, regardless of payer
- EHR: 50% of all applicable patients, regardless of payer
- Claims: 50% of all applicable Medicare Part B patients

ACS supports the data completeness threshold proposed for 2018 for a 90-day minimum reporting period. We do not support the above 50% data completeness thresholds for a 12-month reporting period, as we believe it would greatly increase provider burden and will be infeasible given lack of system interoperability. Continuing a 50% data completeness threshold for a minimum 90-day reporting period will also support program simplicity and stability.

For the 2019 performance year (2021 payment year), CMS proposes 60% data completeness:

- Traditional MIPS Registry: 60% of all applicable patients, regardless of payer
- QCDR: 60% of all applicable patients, regardless of payer
- HR: 60% of all applicable patients, regardless of payer
- Claims: 60% of all applicable Medicare Part B patients

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ACS strongly recommends that CMS—at the very least—review the level of success providers had reporting 50% data completeness for the 2017 performance year before finalizing the 2019 performance year. It is critical that CMS take a measured approach to increasing MIPS reporting requirements before knowing whether MIPS providers are engaged and able to meet the initial requirements.

Further, **ACS strongly recommends that CMS set forth measure implementation criteria that should be met before increasing the data completeness requirement.** For example, the data completeness requirement should not overly burden care or unduly disrupt the patient-clinician encounter. In the future, increased data completeness should apply to measures that are readily available, have automated data flows, and are reliable and valid. The data should also meet minimum standards for impact to quality and improvement, as determined by patient and clinicians.

Selection of MIPS Quality Measures for Individual MIPS Eligible Clinicians and Groups Under the Annual List of Quality Measures Available for MIPS Assessment

Topped Out Measures

ACS opposes the general removal of all measures based on topped out status but supports a modified proposal that would provide an option to transition high value topped out measures into a composite. We believe learning from the aviation industry provides a compelling example to maintain high-value topped out measures. In aviation, a pilot’s pre-flight checklist is always performed at the moment before departure. Although performance on this pre-checklist process is typically high enough to satisfy CMS’ definition of “topped out,” pilots are still required to check these results every time before every flight. Medical care is complex, spanning time, unique patients, and disparate care systems. It is every bit as crucial that we continue to incentivize the long-term tracking of key processes and outcomes— even those that are topped out.

In this rule, after previously noting its intent to remove topped out measures over time, CMS proposes a systematic approach to address topped out quality measures. It proposes a lifecycle for topped out measures where, after a measure benchmark is identified as topped out in the published benchmark for two years, in the third consecutive year it is identified as topped out it will be considered for removal through notice-and-comment rulemaking or the QCDR approval process and may be removed from the benchmark list in the fourth

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year. CMS also proposes to phase in special scoring for measures identified as topped out for two consecutive periods. CMS proposes to score topped out measures differently by applying a 6-point cap, provided it is the second consecutive year the measure is identified as topped out. CMS notes that, because benchmarks are created separately for each submission mechanism, a measure may be identified as topped out for one mechanism but not another, and topped out designation and special scoring only apply to the specific benchmark/submission mechanism. Although this proposal would apply to MIPS measures, CMS also notes that QCDR measures that consistently identified as topped out according to this same timeline would not be approved for use in year four during the QCDR self-nomination period.

CMS proposes to phase in this policy starting with a select set of six highly topped out measures. The first year that these measures could be proposed for removal based on topped out status is 2020, while the first year that all other measures could be proposed for removal is 2021. Two of the six measures proposed under this policy are surgical measures:

- Perioperative Care: Selection of Prophylactic Antibiotic - First OR Second Generation Cephalosporin; and
- Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients).

For multiple reasons, the ACS opposes the general removal of all measures based on topped out status because the policy does not consider the importance of a measure. For one, if CMS discontinues the collection of data on key measures, it will have no way of knowing whether performance regresses or whether the removal of the measure results in lower quality of care over the long term. As noted in the aviation analogy, medical care is complex and spans time, unique patients, and disparate care systems. It is crucial that we continue to incentivize the long-term tracking of key processes and outcomes. Tracking this information is critical for prevention—by receiving information on a possible event can help providers prevent it from occurring altogether. Clinicians could receive credit for maintaining high quality to ensure performance does not change.

We are also concerned that there is not sufficient evidence to truly understand whether a measure is universally topped out. Since programs like MIPS allow for self-selection of measures by clinicians, high median performance may not be representative of the overall clinician community. This is demonstrated in the fact that CMS acknowledges some measures are topped out in one reporting mechanism while not topped out in others. We encourage CMS to further study this topic prior to implementing a policy to remove topped out measures, and we remind CMS that there is a need for

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program stability in the early years of MIPS. **We also strongly encourage CMS to ask measure stewards for different data sources which may demonstrate a gap, as well as looking at whether the measures are topped out across all sub-groups of patients, as there may be certain groups of patients that experience differential performance or reporting rates, such as certain underserved populations.** The longer-term maintenance of key measures in the program will contribute to higher quality care over the long-term and will be less confusing for participants.

In regard to CMS's proposed scoring policy for topped out measures, we recommend that CMS not disincentivise the reporting of these measures for the reasons cited above. We would even prefer that CMS not score these measures differently, especially in the early years of MIPS.

However, an ideal alternative (or perhaps a policy option that could supplement scoring differentials) would be for CMS to include topped out measures as part of a composite, when appropriate. This would provide a pathway for the meaningful inclusion of topped out measures by pairing their reporting with other measures (i.e., report more data to meet measure requirements) and to allow for the ongoing tracking of measures. Implementing a composite will also likely show more variation in performance which will help CMS distinguish performers against a benchmark. Under this alternative, measure stewards could be notified in year one about topped out status, be asked to transition to a composite in year two or three (since it might take time to construct and test the composite), and have the measures finalized for use in MIPS for year four.

As discussed above, there is an argument to be made about the need to maintain high-value process measures—the key is to determine whether a topped out measure is important to deliver the safest, high quality care. Many surgical measures that are deemed topped out tell an important story as part of the care continuum. For example, measuring antibiotics before surgical care was once adequate. However, we have come to realize that to track patients optimally, we need checklists of interrelated processes that are closely tied to outcomes (e.g., sepsis bundles). Additionally, surgical science has advanced around enhanced recovery protocols, commonly referred to as Enhanced Recovery After Surgery (ERAS). ERAS is a more comprehensive patient-centered approach to optimize patient care which requires nutritional plans, shared IV fluid strategies, an analgesic program with opioid limits, infection prevention protocols and outcome tracking. The multidisciplinary nature of successful ERAS strategies are well-documented and widely-supported throughout the medical literature. By pulling all the surgical teams together in a checklist for these processes, the goal is to achieve 100 percent performance on

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the processes and greater track of outcomes, including patient-reported outcomes (PROs). **This measure philosophy represents a mechanism to appropriately value single measures currently determined to be “topped out.” Instead, we encourage CMS to recognize composites of high value process measures that can demonstrate consistency and highly reliable care processes.**

To this end, we recommend applying the alternate proposal to the two perioperative care measures recommended for removal: 1) Perioperative Care: Selection of Prophylactic Antibiotic - First OR Second Generation Cephalosporin and 2) Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients). **Before CMS removes these surgical measures, we urge CMS to consult stakeholders and literature on the importance of these measures for patient safety and if stakeholders agree these measures are key delivering safe surgical care, consider that they be included in a perioperative composite.** In the case of the perioperative care measures, both of these measures have been National Quality Forum (NQF)-endorsed, and therefore met the “Importance to Measure and Report” criteria.⁶ We also strongly encourage CMS to ask measures stewards for different data sources, which may demonstrate a gap, as well as look at whether the measures are topped out across all sub-groups of patients, as there may be certain groups of patients who experience differential performance or reporting rates, such as certain underserved populations.

We also seek clarification on whether CMS’s proposal to apply special scoring in years two and three of topped out status would also apply to QCDR measures. It is not entirely clear from the rule. We are concerned that CMS’s three-year vetting of measures could reduce the ability of surgical subspecialties to develop and strengthen new measures. Congress created the QCDR mechanism to fill critical gaps in the traditional quality measure sets and to ensure that clinicians have access to more meaningful and relevant measures. The combination of topped out measures and the slow approval of QCDR measures creates an effect that is counter to the statutory purpose of QCDRs in regards to being innovative and targeting the needs of different specialties. ACS believes that the same concept should be applied to QCDRs, such as recommending topped out measures be included in a composite. However, the topped out measure process should not interfere with the innovate and comparatively more efficient QCDR measure review and approval process.

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⁶ Measure Evaluation Criteria . (n.d.). Retrieved from

http://www.qualityforum.org/Measuring_Performance/Submitting_Standards/Measure_Evaluation_Criteria.aspx



CMS also proposes not to include Web Interface measures in its topped out measure policy since these measures align with the Shared Savings Program and because reporters would not have the ability to select other measures if these were removed. The ACS does not believe it is reasonable or fair to exclude Web Interface measures. Whatever policies that CMS finalizes related to topped out measures should be adopted for Web Interface measures, as well. If this results in fewer measures available to users of the Web Interface then CMS should make accommodations to ensure additional measures or reporting mechanisms are available.

In summary, the ACS strongly opposes the removal of all topped out measures and urges CMS to consider alternative policy options for how to maintain high value and meaningful measures. While we understand CMS’s concerns with these measures, we do not believe that CMS has an adequate understanding of the impact of removing or otherwise disincentivizing the collection of these data. We also believe that regular modifications to the MIPS measure set is not only frustrating and burdensome for clinicians but that it does not allow for the long-term evaluation of a measure’s impact. Furthermore, we believe that CMS’s proposal to measure improvement, in addition to achievement, is a sufficient incentive to ensure that clinicians also select non-topped out measures.

Quality Measures Determined to be Outcome Measures

The Quality performance category of the MIPS program requires the reporting of at least one outcome measure and provides an opportunity to earn bonus points to the Quality performance score for reporting additional outcome measures. CMS explains that for most measures, the Agency currently uses the measure designation as determined by the measure steward and the NQF. If it is unclear, CMS utilizes the Blueprint for the CMS Measures Management System, which defines an outcome measure as follows: “an outcome of care is a health state of a patient resulting from health care. Outcome measures are supported by evidence that the measure has been used to detect the impact of one or more clinical interventions. Clinical analysts are utilized to evaluate the measure.”⁷

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⁷ Blueprint for the CMS Measures Management System [PDF]. (2017, May). CMS.



ACS asks CMS to specifically include Patient Reported Outcome Measures (PROMs) within the definition of an outcome measure. This is important for many reasons, including:

- **The majority of surgical procedures are elective with the goal of improving a patient’s quality of life and/or function.**^{8,9,10} In NSQIP for calendar year 2016, there were only 20.4% non-elective operations out of 998,000 cases. Therefore, for most procedures, the outcome reported by the patient and for which the patient is the best source of success of the procedure. Additionally, most elective procedures have very few serious clinical events which, again, highlights the challenges with case volume, discussed above.
- **Misclassification due to low statistical power when measuring clinical surgical outcomes on the level of the physician.** Confidence intervals for discerning differences or variances in surgeons are so large that they overlap—one cannot detect an effect when there is an effect there to be detected. For example, with the use of high quality clinical data from ACS NSQIP, ACS has demonstrated that the needed case volume is too high for most surgeons to be accurately ranked solely by their individual outcomes. In a recent NSQIP study, the sample size needed to achieve acceptable statistical reliability (0.7) for SSI was 254 cases, and 1,985 cases for mortality. The high case volume required is especially difficult given the regulatory requirements of the MIPS program which only allow for a maximum of 12 months of a data and a 20-case minimum sample size. In contrast, PROMs will have a higher case volume because they are not just relevant to rare outcomes (SSI, mortality, readmission, etc.)—they are relevant to all patients within an episode.
- **PROMs are better understood by Medicare patients and are therefore much more helpful in the process of choosing a surgical provider.**

⁸ Gale, S. C., Shafi, S., Dombrowskiy, V. Y., Arumugam, D., & Crystal, J. S. (2014). The public health burden of emergency general surgery in the United States: a 10-year analysis of the Nationwide Inpatient Sample—2001 to 2010. *Journal of Trauma and Acute Care Surgery*, 77(2), 202-208.

⁹ Scott, J. W., Olufajo, O. A., Brat, G. A., Rose, J. A., Zogg, C. K., Haider, A. H., ... & Havens, J. M. (2016). Use of national burden to define operative emergency general surgery. *JAMA surgery*, 151(6), e160480-e160480.

¹⁰ Ingraham, A. M., Cohen, M. E., Raval, M. V., Ko, C. Y., & Nathens, A. B. (2011). Comparison of hospital performance in emergency versus elective general surgery operations at 198 hospitals. *Journal of the American College of Surgeons*, 212(1), 20-28.

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Cost Performance Category

Weighting in the Final Score

In the CY 2017 QPP rule, CMS finalized for the transition year a policy to weight the cost performance category at 0 percent in the final score in order to give clinicians more opportunity to understand the attribution and the scoring methodology and gain more familiarity with the measures through performance feedback. CMS previously finalized a Cost performance category weight of 10 percent for the 2020 MIPS payment year. For the 2021 MIPS payment year and beyond, the Cost performance category will have a weight of 30 percent of the final score. In the CY 2018 QPP proposed rule, CMS proposes to change the weight of the Cost performance category from 10 percent to 0 percent for the 2020 MIPS payment year. **We thank CMS for maintaining the Cost performance category weight at 0 percent for another year.** We do not believe that the Cost performance category is currently ready to be scored as there are too many undetermined factors.

CMS expressed concern that assigning a 0 percent weight to the Cost performance category for the 2020 MIPS payment year may not provide a smooth enough transition for integrating cost measures into MIPS given that in 2021 the cost performance category will be used to determine 30 percent of the final score for MIPS eligible clinicians. We support maintaining the Cost performance category weight at 0 percent for another year despite the issue that CMS raised. We still have a number of concerns with the Cost performance category, including:

- Ongoing concerns with the Medicare Spending Per Beneficiary (MSPB) measure (discussed in more detail below);
- The fact that the episode-based cost measures that CMS plans to include have not yet been developed and tested, and
- Uncertainties surrounding the patient relationship codes.

As such, the benefit of maintaining the cost performance category at 0 percent for another year outweighs the difficulty of transitioning from 0 percent to the statutorily-mandated 30 percent in 2021.

Cost Criteria

MEASURES PROPOSED FOR THE MIPS COST PERFORMANCE CATEGORY

Total Per Capita Cost and MSPB Measures

For the 2018 MIPS performance period and future performance periods, CMS

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is proposing to include in the Cost performance category the Total Per Capita Cost measure and the MSPB measure as finalized for the 2017 MIPS performance period.

For the MSPB measure, CMS does not propose any changes to the methodologies for payment standardization, risk adjustment, and specialty adjustment from the policies that were finalized in the CY 2017 QPP final rule. We restate our concerns that the 0.4 reliability threshold used for the MSPB measure is extremely low when the minimum in the literature accepted is 0.7 for “acceptable” reliability. ACS believes that CMS should not accept the lower limit of “moderate” reliability (0.4) and we do not see the value in setting such a low bar for reliability. **We strongly encourage CMS to demonstrate “good” reliability (0.8) for the MSPB measure so that MIPS clinicians have confidence in the program and can learn to improve the value of the care they deliver.**

In the CY 2017 QPP final rule CMS also finalized two technical changes to the MSPB measure:

- Removal of the specialty adjustment that accounted for the case-mix difference across the patient population; and
- Modification of the cost ratio used within the equation to evaluate the difference between observed and expected episode cost at the episode level before comparing the two at the individual or group level.

We restate our opposition to these changes, given that CMS has not provided further evidence to support this policy. CMS stated that the specialty adjustment it is not necessary and may not be needed, yet CMS did not provide data to support this statement. CMS initially applied the specialty adjustment to all cost measures, publicly supporting this decision with evidence and educational materials, and yet CMS then finalized it for removal without an explaining why it is no longer necessary. **Due to this lack of transparency, we cannot support these previously finalized changes to the MSPB measure. In general, we urge CMS to strengthen the measure reliability, validity, and risk adjustment methodology for the MIPS program, not lower the bar.**

We also note the importance of the sociodemographic status (SDS) factors and how these factors can impact outcomes for providers who care for patients of diverse backgrounds. When developing policies surrounding the Cost performance category, CMS should consider the increased costs in caring for these patients, and we ask that CMS adjust for those differences when calculating the Cost performance category in future years.

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Episode-Based Measures

For the 2018 MIPS performance period, CMS is not proposing to include in the Cost performance category the 10 episode-based measures that CMS adopted for the 2017 MIPS performance period in the CY 2017 QPP final rule. CMS will instead work to develop new episode-based measures, which the agency plans to include in the Cost performance category for the 2018 MIPS performance period. CMS plans to continue feedback on episode-based measures as appropriate but is unable to provide a list at this time.

ACS continues to assert that physicians should not be held accountable for cost performance until CMS has carefully tested the episode-based cost measures that are under development. We agree that specific episode-based cost measures will help ensure more fair comparisons and alleviate the need for many of the complex adjustments to data that are required with total per capita cost measures. It is important for CMS to ensure that practices are being compared to similarly situated practices (geography, specialty mix, patient mix, etc.). **We encourage continued testing of the episode-based cost measures under development—including the testing of ICD-10 reliability and validity as well as attribution-related issues. We also strongly urge CMS to align these measures with quality measures for a more comprehensive value measurement.**

Lastly, it is important that CMS implement a mechanism to account for all pharmaceutical costs when evaluating physician resource use. It is also important to identify scenarios where savings can be achieved by prescribing less expensive yet equally effective drugs.

Patient Relationship Categories and Codes

CMS is in the process of developing patient relationship categories and codes, as required by MACRA, to be included on Medicare claims by January 1, 2018. These categories and codes can also be used to attribute cost to clinicians providing care within episodes. ACS has previously commented that it has been difficult to provide cogent feedback on this issue when it is unclear what episodes/claims the patient relationship categories and codes will be used for, what level of accountability will be tied to each category, or how the categories will affect payment under the QPP, and specifically under the Cost Performance category. We have raised a number of questions regarding these codes such as whether the codes will be self-assigned at the point of care or at the point of billing, how a change in the physician's relationship with the patient over time affects the assigned code, and how the categories apply to team-based care and cross coverage where multiple physicians are in charge of

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a patient over different points in time. As such, we appreciate and support CMS' proposal in the CY 2018 Medicare Physician Fee Schedule proposed rule to make the use of these codes voluntary in 2018.

FACILITY-BASED MEASUREMENT AS IT RELATES TO THE COST PERFORMANCE CATEGORY

CMS proposes to implement facility-based measures, specifically the HVBP Program for assessment under MIPS for both the Quality and Cost performance categories. We believe that assessment under the Cost category should focus on episode-based risk-adjusted measures that align with measures used for facility-based reporting in the Quality performance category. The HVBP Program does not include such measures, rather it relies on the MSPB measure alone to assess resource use. As noted above, we have a number of concerns with the MSPB measure. In addition, episode-based risk-adjusted measures are preferable because they would provide a fairer way to compare clinicians on measures that are relevant to the care they provide. As such, we recommend that episode-based risk-adjusted measures be built into any mechanism to assess clinicians on resource use, including for facility-based measurement.

Improvement Activities Category

Background

The ACS would like to thank CMS for providing stability in the IA component of MIPS and for its continued openness to considering additions to its list of approved activities. While we were disappointed that most of our suggestions were not included, we look forward to working with CMS in the optimization of those activities that were accepted toward the overall goal of improving clinical practice and outcomes. We very much hope CMS will be open to the reconsideration of some of our previous submissions, in modified form, with its next submission and review process.

Contribution to the Final Score

Per our comment above, the ACS was pleased to find consistency from the 2017 performance year in both the 15% percent of the final score attributed to the Improvement Activities as well as that the criteria for "full credit" remained at 40 points. That said, and based on CMS's own definition for high weighting provided in the proposed rule, we would ask that CMS reconsider its decision to ascribe a medium weighting to use of the Enhanced Recovery After Surgery (ERAS) protocols. ERAS involves care coordination with the patient

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and all the care providers across the timeline of the episode. It is the ACS' firm belief that ERAS epitomizes the criteria for a high value activity by directly addressing an area with the greatest impact on beneficiary care, safety, health and well-being.

Our rationale for this argument is based in the following:

The Physician Quality Reporting Initiative (PQRI) first began in 2007 as required by the Tax Relief and Health Care Act when CMS launched performance measures linking Medicare provider payments to quality. This then evolved into the Physician Quality Reporting System (PQRS) and was made permanent under MIPPA in 2008, acting as a “pay-for-reporting” program rewarding providers financially for reporting health care quality data to CMS. Most recently, MACRA brought us to the QPP, with the goal of moving physicians from MIPS to APMs. MACRA eliminated The Sustainable Growth Rate (SGR), established in 1997 as a way of controlling the costs of Medicare payments to physicians, and instead incentivized payments based on quality and value of care. However, measurement science has demonstrated that case specific or surgeon specific outcome measures lack reliability and validity for discernment in fiscal reward or penalty programs. This had led to a call for better ways to assess quality of patient care.

Across the same decade, enhanced recovery protocols, commonly referred to as ERAS, has sparked excitement in the surgical community. ERAS is an innovative approach to delivering standardized and evidence-based care and has been shown to reduce surgical complications, improve patient satisfaction, and decrease length of stay (LOS) and associated hospital costs without increasing readmission rates.^{11,12,13} The success of ERAS lies in uniting the entire perioperative team in the spirit of improving patient care. Its efforts span across all phases of care (preoperative, intraoperative, postoperative, and post-discharge) as well as medical specialties (surgery, anesthesiology, nursing, pharmacy and physical therapy). The ACS, in collaboration with The Agency for Healthcare Research and Quality (AHRQ) and Johns Hopkins Armstrong Institute for Patient Safety and Quality, has developed the Improving Surgical

¹¹ Thiele, R. H., Rea, K. M., Turrentine, F. E., Friel, C. M., Hassinger, T. E., Goudreau, B. J., ... & McMurry, T. L. (2015). Standardization of care: impact of an enhanced recovery protocol on length of stay, complications, and direct costs after colorectal surgery. *Journal of the American College of Surgeons*, 220(4), 430-443.

¹² Geltzeiler, C. B., Rotramel, A., Wilson, C., Deng, L., Whiteford, M. H., & Frankhouse, J. (2014). Prospective study of colorectal enhanced recovery after surgery in a community hospital. *JAMA surgery*, 149(9), 955-961.

¹³ Greco, M., Capretti, G., Beretta, L., Gemma, M., Pecorelli, N., & Braga, M. (2014). Enhanced recovery program in colorectal surgery: a meta-analysis of randomized controlled trials. *World journal of surgery*, 38(6), 1531-1541.

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Care and Recovery (ISCR) program to implement evidence based enhanced recovery protocols in multiple surgical specialties across the U.S.

Within ISCR, individual elements of care or process measures are measured and targeted for quality improvement. Further, it incorporates patient-reported experience and patient-reported outcomes as a component of the overall care paradigm. This model thus lends itself to the episode-based measure framework. Most care, including surgical care, involves episodes of care with discrete patient goals. The past decade of ERAS research and the ACS ISCR program has identified key process measures that are associated with better patient outcomes, which include both traditional outcomes measures, such as mortality and morbidity, but also patient-reported outcomes. These process measures are best recognized in the phases of care across the episode of patient care. Linking these high value process measures with both traditional outcomes and patient-reported outcomes represent the next level of measurement science. Assessing these process measures instead of single outcome measures will provide a more accurate representation of the quality of healthcare delivery and is an opportunity to build measures in a modern framework for a given episode. ERAS has the potential to transform surgical care delivery across the nation. It focuses on improving each incremental step in the healthcare delivery pathway, not just the end result. To achieve the ultimate goal of better patient care and quality, we have the opportunity to align the payment.

Improvement Activities Data Submission Criteria

The ACS applauds CMS' decision to maintain its policy of requiring reporting of IA by attestation and the reporting mechanisms associated with that attestation. We believe that CMS's decision to maintain this policy into future years is the correct decision. Further, we also appreciate the consideration given to those MIPS eligible clinicians or groups who may utilize multiple reporting mechanisms for reporting IA data in their practice. Under the proposed rule, they will be able to use as many different submission mechanisms as necessary to meet requirements rather than being constrained to a single mechanism as they were by the CY2017 Quality Payment Program final rule. It is important to note that ACS does not support multiple submission mechanisms for the Quality performance category, for reasons discussed in detail with the Quality section of this letter.

We are also in agreement with CMS' goal of promoting greater participation with the IA component of the QPP and accordingly, understand the desire to move beyond the point whereby if one MIPS eligible clinician in a group completed an improvement activity for a continuous 90-day performance period, the entire group would receive credit for that activity. We also share

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CMS' concerns relative to increasing burdens on smaller practices and the potential unintended consequence of incentivizing groups who are exceeding the threshold to gravitate toward the threshold.

In moving forward toward the establishment of a different minimum threshold for groups, we would urge CMS to take into consideration both the size and the specialty composition of the groups involved. At the risk of potentially establishing criteria that are overly complex, establishing a rigid, one-size-fits-all threshold has the potential to hinder the overall policy goal of the IA component.

In sum, the ACS believes that maintaining stability and consistency in the requirements for achieving full credit in the IA component is appropriate, laudable and will facilitate the greatest opportunity for CMS to meet its goals ascribed this component of MIPS.

Special Consideration for Small, Rural, or Health Professional Shortage Areas Practices

As CMS well knows, the provider group perhaps most concerned about the burdens imposed by the QPP are those in small practices or those in rural areas. Accordingly, the ACS thanks CMS for proposing to maintain the separate, less demanding criteria for full credit of one high value or two medium value activities for those in small and rural practices. We believe this will be particularly welcomed by surgeons in these practice situations.

Improvement Activities Subcategories

The ACS again thanks CMS for including its Surgical Risk Calculator in its inventory of approved IAs. That said, we believe CMS should seriously consider changing the subcategory of IA to which the Surgical Risk Calculator is assigned and that CMS similarly consider making use of the Surgical Risk Calculator a high value activity under specific circumstances. As is discussed in detail below, we will also ask that the Surgical Risk Calculator be separated from the ERAS protocols.

Specifically, we believe that use of the Surgical Risk Calculator would be better classified on its own as a separate activity in the Beneficiary Engagement subcategory rather than being assigned to the Patient Safety subcategory. Our rationale for requesting this change is that use of the Surgical Risk Calculator is primarily an activity that promotes shared decision making. Further, while we agree with CMS that attestation to the simple use of the Surgical Risk Calculator for a period of 90 consecutive days should

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continue to be weighted as a “medium” value activity, we would ask that use of the Surgical Risk Calculator be ascribed a “high” value in those circumstances where its use is documented as part of the informed consent process for a minimum of 50 percent of all major surgical procedures performed by the individual provider.

Improvement Activity Inventory

The ACS applauds CMS inclusion of new IAs, several of which will be applicable to surgeons. ACS supports the inclusion of the following IAs:

- Clinician Leadership in Clinical Trials
- Provision of Education Opportunities for New Clinicians
- CDC Training for both Antibiotic Stewardship and the Prescribing of Opioids for Chronic Pain; and
- Anticoagulation Medication Management for Invasive Procedure or Surgery.

As was previously stated, we look forward to working with CMS in the optimization of the activities ACS submitted, which CMS has accepted, and we sincerely hope CMS will be open to the reconsideration of some of our previous submissions, in modified form, with its next submission and review process.

Regarding to the changes to IAs proposed in Table G, the ACS would again request that Surgical Risk Calculator and the ERAS protocols be separated.

- As was discussed previously in sections above, we believe the Surgical Risk Calculator falls more appropriately into the Beneficiary Engagement Category rather than the Use of Patient Safety Tools subcategory. Depending on the rigor of the circumstances under which it is utilized, **we ask that use be assigned either a “medium” value, (simple attestation to use for 90 consecutive days) OR “high” value, (use is documented as part of the informed consent process for a minimum of 50 percent of all major surgical procedures performed by the individual provider).**
- The ACS agrees that the ERAS protocols are appropriately categorized as a Patient Safety Tool. However, based on the evidence presented above, **we ask CMS to ascribe a “high” value to the use of ERAS.** CMS has defined the criteria for a “high” value activity as one that directly addresses an area with the greatest impact on beneficiary care, safety, health and well-being. Based on our experience with the ERAS protocols as documented in the evidence presented above, the ACS firmly believes ERAS epitomizes these criteria.

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Approach for Adding New Subcategories

The ACS agrees with CMS' criteria for adding new subcategories for the IAs and believes that it would be appropriate to approach such in the future utilizing the notice and comment rulemaking.

Advancing Care Information Performance Category

Background

As we transition toward episode-based care with shared accountability, the need for digital information to flow between all members of a team and relevant systems will grow more complex, yet is critical to successful patient care. Therefore, a national model for accelerating interoperability across EHRs, mobile devices, registries and patient clouds which support this transition is critical to the future of our healthcare system. **The current digital environment cannot deliver the information needed by the surgical team to provide even basic care, and the current ACI program perpetuates the continued development of one-off inoperable and siloed EHR products.** The ACI objectives and measures, including those based on Stage 3 Meaningful Use (i.e., 2015 Edition certified EHR technology), do not reflect true interoperability or support bidirectional health information exchange across multiple systems and platforms. In fact, the current ACI measures detract from progress toward a learning healthcare system and simply add to reporting burden for surgeons. **It is critical for CMS to realize that we are not going to solve interoperability problems with the current ACI approach which focuses solely on EHRs.**

It is perplexing that 13 years after President George W. Bush issued Executive Order (EO) 13335 “to provide leadership for the development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care” and to establish the position of a National Coordinator for Health Information Technology (IT) (ONC) within the Office of the Secretary of Health and Human Services that we continue to look for federal leadership when it comes to fostering the development and adoption of open source interoperability standards to deliver quality care for our patients. The lag between regulation and where the health IT industry is in regard to innovation continues to widen despite billions of taxpayer dollars spent so that healthcare providers could purchase health IT systems. The systems required for ACI participation (and previously Meaningful Use) do not support the envisioned nationwide health information network that is essential to advance the value-driven healthcare

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system we strive for because they do incentivize the use of the cutting-edge technology.

As we stated in recent correspondence with Secretary Price, to support the transition of health care and give providers the tools they need, we must translate the ONC Interoperability Roadmap into an operational plan. CMS and ONC must work together to address the significant shortcomings of the ACI performance category, starting with a more robust set of objectives and measures that capture actual functions of interoperability across multiple disparate providers, patients and systems. To this end, we have the following recommendations:

1. CMS should collaborate with ONC to aid specialty medicine and other stakeholders in the process of creating clinical conceptual models as a necessary first step toward build the technical logic models and applied terminologies and value sets needed for interoperability. This is the process of translating clinical content in its context to enable the level of interoperability needed by the clinical team to provide the best care. Clinical interoperability then needs to be translated into technical interoperability to allow for the digital exchange of information for a specific purpose.
2. To enable digital health information interoperability across EHRs, mobile devices, registries and patient clouds, we propose that the appropriate HHS agency assume a leadership in partnership with the clinical community by serving jointly as a convening role for interoperability. This should include establishing a framework, processes, overall governance, priorities, policies, support for resources needed to convene clinical content and context expertise alongside technology and standards expertise. The physician community, in collaboration with other stakeholders, would then select specific clinical domains to create interoperable solutions, and those domains would lead to open source interoperable digital standards.
3. EHR certification standards should be created to require EHRs to be compliant with the described open source digital standards that meet criteria for clinical interoperability. This would greatly aid in data liquidity, which would eliminate data blocking, and enable patient cloud environments.

We believe interoperable solutions are best characterized by understanding use cases, which can be divided into four general categories, starting with EHR interoperability, with data streams moving bi-directionally across EHRs, mobile devices, registries and clouds where the data can be used to support Clinical Decision Support, and eventually result in artificial intelligence or computer adaptive learning:

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1. EHR ↔ EHR
2. EHR ↔ EHR ↔ mobile device
3. EHR ↔ EHR ↔ mobile device ↔ registries/clouds with Clinical Decision Support guidelines
4. EHR ↔ EHR ↔ mobile device ↔ registries/clouds with Clinical Decision Support guidelines ↔ machine learning / artificial intelligence

To illustrate the vision of interoperability, the ACS is currently working on a conceptual framework for cancer interoperability. We recognize an overhaul of the current program is not possible in a short timeframe, however, we need fundamental reforms in the ACI program to support a national model for accelerating interoperable solutions, which starts with the objectives and measures on which they are scored in the current ACI performance category. We look to CMS to recognize that what is meaningful to surgeons is their ability to engage with patients, care team members, clinical data registries and other data sources to improve surgical outcomes starting with the decision for surgery and throughout each stage of treatment at the point of care. **A query of the clinical data registry provides a wealth of information on the most appropriate course of action for each individual patient based on their unique clinical and social circumstances, which is a far more relevant and impactful use of health IT than much of what surgeons are currently scored on in the ACI performance category.** We look forward to working with CMS on ways to improve the use of digital health information that will support care across systems and providers.

Scoring

PERFORMANCE SCORE

CMS proposes if a MIPS eligible clinician fulfills the Immunization Registry Reporting Measure, the MIPS eligible clinician would earn 10 percentage points in the performance score. If a MIPS eligible clinician cannot fulfill the Immunization Registry Reporting Measure, CMS proposes that the MIPS eligible clinician could earn 5 percentage points in the performance score for each public health agency or clinical data registry to which the clinician reports for the following measures, up to a maximum of 10 percentage points: Syndromic Surveillance Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Clinical Data Registry Reporting (or Syndromic Surveillance Reporting or Specialized Registry Reporting under the 2018 ACI Transition set). A MIPS eligible clinician who chooses to report to more than one public health agency or clinical data registry may receive credit in the performance score for the submission to more than one agency or registry;

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however, the MIPS eligible clinician would not earn more than a total of 10 percentage points for such reporting.

While we appreciate CMS' intent not to penalize those without access to immunization registries, this proposal diminishes the value of reporting to specialized and clinical data registries by only awarding 5 percentage points for reporting to such registries. Eligible clinicians who do not have access to an immunization registry should be able to earn the full 10 percentage points for reporting to a single other recognized registry, such as a specialized or clinical data registry. **We urge CMS to award 10 points for all other registry types, beyond the immunization registry, while maintaining the policy of awarding 5 additional points for reporting to any other type of registry in the Bonus Score.**

Performance Periods for the Advancing Care Information Performance Category

As it did for CY 2017 and CY 2018, CMS proposes a performance period of one full year for the ACI performance category in CY 2019 QPP Year 3 to align with the overall MIPS performance period to ensure all four performance categories are measured and scored based on the same period of time. CMS also proposes to accept a minimum of 90 consecutive days of data in CY 2019. **Given current program requirements, we support the proposal to accept a minimum of 90 consecutive days of data, and urge CMS to finalize this as proposed.**

Certification Requirements

CMS proposes that MIPS eligible clinicians may use EHR technology certified to either the 2014 or 2015 Edition certification criteria, or a combination of the two for the 2018 performance period. CMS also proposes to offer a bonus of 10 percentage points under the ACI performance category for MIPS eligible clinicians who report the ACI Objectives and Measures for the performance period in 2018 using only 2015 Edition CEHRT. Given current program requirements, we support the proposal to allow providers to use either 2014 or 2015 CEHRT or a combination of the two. We do not believe, however, that moving to 2015 Edition CEHRT enhances a physician's ability to provide higher quality care. **Therefore, we do not support bonus points for practices that adopt 2015 Edition CEHRT in CY 2018.** As discussed earlier, there is no evidence that demonstrates EHRs improve the quality of surgical care. Therefore, we do not support efforts which focus on the further proliferation of a siloed EHR approach to the use of HIT. We encourage CMS to incentivize investments in a national model for accelerating interoperability across EHRs,

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mobile devices, registries and patient clouds which support the transition toward episode-based care, as discussed in greater detail above.

Objectives and Measures

ADVANCING CARE INFORMATION OBJECTIVES AND MEASURES SPECIFICATIONS

CMS proposes to maintain for the 2018 performance period the ACI Objectives and Measures as finalized in the 2017 QPP final rule with the modifications. CMS has split the Specialized Registry Reporting Measure that it adopted under the 2017 Advancing Care Information Transition Objectives and Measures into two separate measures – Public Health Registry and Clinical Data Registry Reporting – to better define the registries available for reporting. CMS proposes to allow MIPS eligible clinicians and groups to continue to count active engagement in electronic public health reporting with specialized registries. Specifically, CMS proposes to allow these registries to be counted for purposes of reporting the Public Health Registry Reporting Measure or the Clinical Data Registry Reporting Measure beginning with the 2018 performance period. A MIPS eligible clinician may count a specialized registry if the MIPS eligible clinician achieved the phase of active engagement as described under “active engagement option 3: production” in the 2015 EHR Incentive Programs final rule with comment period, meaning the clinician has completed testing and validation of the electronic submission and is electronically submitting production data to the public health agency or clinical data registry.

Under the ACI category in 2017, CMS gave clinicians the option to demonstrate “active engagement” at three different levels, depending on readiness:

- **Active Engagement Option 1—Completed Registration to Submit Data:** The EP registered to submit data with the PHA, or where applicable, the CDR to which the information is being submitted; registration was completed within 60 days after the start of the EHR reporting period; and the EP is awaiting an invitation from the PHA or CDR to begin testing and validation. This option allows providers to meet the measure when the PHA or the CDR has limited resources to initiate the testing and validation process. Providers who have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period.
- **Active Engagement Option 2—Testing and Validation:** The EP is in the process of testing and validation of the electronic submission of

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data. Providers must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within an EHR reporting period would result in that provider not meeting the measure.

- **Active Engagement Option 3—Production:** The EP has completed testing and validation of the electronic submission and is electronically submitting production data to the PHA or CDR.

The ACS strongly urges CMS to maintain flexibility by allowing clinicians to continue to demonstrate “Active Engagement” using any of these three current options. By maintaining these three options, providers who invest in registries will still be able to get credit for this measure if the registry is working towards, but has not yet achieved the “production” stage. Many specialty society-sponsored registries have invested heavily in resources and processes to ensure seamless integration with EHRs, but still are not where they would ideally like to be for reasons that are often outside their control (e.g., ongoing lack of interoperability standards, the need to work with numerous EHRs that each rely on slightly different standards, the need to get buy-in from institutions/practices that own these EHRs, etc.). The clinicians using these registries should still be recognized for investing time and resources in the implementation and use of a registry to improve patient care. **We also urge CMS and ONC to work together to provide clearer guidance on the requirements (including documentation requirements) associated with each of these stages of “Active Engagement” since many clinicians and registry vendors still do not fully understand what distinguishes one stage from another.**

2017 AND 2018 ADVANCING CARE INFORMATION TRANSITION OBJECTIVES AND MEASURES SPECIFICATIONS

CMS proposes several edits to the 2017 ACI Transition Objectives and Measures for the ACI performance category of MIPS for the 2017 and 2018 performance periods. For example, CMS proposes to define “timely” as within 4 business days for the Provide Patient Access measure to align with the EHR Incentive Program. CMS also proposes to replace the term “health care clinician” with the more appropriate term “health care provider” in the Send a Summary of Care measure, which was an inadvertent error. Other proposed changes correct similar inadvertent errors on the part of CMS. Until an overhaul of the ACI performance category is undertaken, we support the modifications as proposed and urge CMS to finalize them as described.

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EXCLUSIONS

CMS proposes to add exclusions to the measures associated with the Health Information Exchange and Electronic Prescribing objectives required for the base score, which it proposes would apply beginning with the 2017 performance period. The exclusions are as follows:

ACI Measure Set	ACI Objective	ACI Measure	Proposed Exclusion
ACI Transition Objectives and Measures	Health Information Exchange	Health Information Exchange	<i>Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.</i>
ACI Transition Objectives and Measures	Electronic Prescribing	e-prescribing	<i>Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.</i>
ACI Objectives and Measures	Health Information Exchange	Send a Summary of Care	<i>Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.</i>
ACI Objectives and Measures	Health Information Exchange	Request/Accept Summary of Care	<i>Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.</i>
ACI Objectives and Measures	Electronic Prescribing	e-prescribing	<i>Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.</i>

Given current program requirements, we support these exclusions and urge CMS to finalize these as proposed.



Additional Considerations

21ST CENTURY CURES ACT

CMS proposes to rely on new authorities granted under the 21st Century Cures Act to provide for significant hardship exceptions under the ACI performance category under MIPS. CMS also proposes not to apply the 5-year limitation to significant hardship exceptions. In addition, as authorized under the 21st Century Cures Act, CMS proposes a new significant hardship exception for MIPS eligible clinicians who are in small practices, as well as for those who have EHR technology that has been decertified. In light of current program requirements, we support these exemptions as described and urge CMS to finalize these policies as proposed. We continue to believe a complete overhaul of the ACI performance category is necessary to make adoption and use of health information technologies and digital health information meaningful for surgeons and other physician specialties.

HOSPITAL-BASED MIPS ELIGIBLE CLINICIANS

CMS proposes to modify its policy to include covered professional services furnished by MIPS eligible clinicians in an off-campus-outpatient hospital (POS 19) in the definition of hospital-based MIPS eligible clinician. CMS proposes to add POS 19 to its existing definition of a hospital-based MIPS eligible clinician— which includes POS 21, POS 22, and POS 23— beginning with the performance period in 2018. CMS states that clinicians who meet the definition for hospital-based do not have the option to report ACI measures applicable to them in MIPS, and CMS previously finalized that the ACI performance category would be reweighted to 0% of the MIPS final score. **We generally support this proposal, but encourage CMS to reweight half of the ACI score to IA and half to Quality.** As proposed, we believe the Quality performance category will be too heavily weighted based on measures that lack validity and reliability. Additionally, giving more weight to IA will decrease administrative burden by reducing the amount of data required for submission because IA is attestation. We also encourage CMS to look across all applicable places of service, in the aggregate, when determining whether a clinician is hospital-based. Currently, CMS only looks at one setting (e.g., did you provide 75% of services in the inpatient setting OR the outpatient hospital setting, but not both). Many surgeons practice in multiple hospital settings, where they lack control over EHR decisions. Revising this calculation would help them to meet the threshold to receive an exemption from the ACI category.

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Under separate authority granted under the 21st Century Cures Act, and in an effort to further expand the ACI exemption for clinicians who practice in settings where they lack direct control over EHR decisions, CMS proposes to define an ASC-based MIPS eligible clinician as a MIPS eligible clinician who furnishes 75% or more of his or her covered professional services in Place of Service (POS) 24. CMS requests comments on this proposal and solicits comments as to whether other POS codes should be used to identify a MIPS eligible clinician's ASC-based status or if an alternative methodology should be used. CMS notes that the ASC-based determination will be made independent of the hospital-based determination.

ACS supports the proposal to define an ASC-based MIPS eligible clinician as a MIPS eligible clinician who furnishes 75% or more of his or her covered professional services in POS 24. As we noted earlier, ACS encourages CMS to look across all applicable places of service, in the aggregate, when determining whether a clinician is hospital-based and/or ASC-based. Currently, CMS only looks at one setting (e.g., did you provide 75% of services in the inpatient setting OR the outpatient hospital setting, but not both). Many surgeons practice in both ASCs and hospitals, and ACS believes that if CMS considered multiple settings this would help relieve burden among surgeons to help them meet the 75% threshold.

TIMELINE FOR SUBMISSION OF REWEIGHTING APPLICATIONS

CMS proposes to change the submission deadline for the application as the agency believes that aligning the data submission deadline with the reweighting application deadline could disadvantage MIPS eligible clinicians. CMS states that the QPP Exception Application will be used to apply for the following exceptions: Insufficient internet connectivity; Extreme and uncontrollable circumstances, Lack of control over the availability of CEHRT; Decertification of CEHRT; and Small practices. CMS proposes to change the submission deadline for the 2017 performance period to December 31, 2017, or a later date specified by the agency, which would help MIPS eligible clinicians learn whether their application is approved prior to the data submission deadline for the 2017 performance period, March 31, 2018. CMS explains that if a provider submits data after an application has been submitted, the data would be scored, the application would be voided and the ACI performance category would not be reweighted. ACS supports the proposal to change the data submission deadline to December 31, 2017 because we believe it will reduce the reporting burden for those providers who are granted an exclusion, as well as prevent a voided application to reweight the ACI score.

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APM Scoring Standard for MIPS Eligible Clinicians in MIPS APMs

Overview

In the CY 2017 QPP rule, CMS finalized the MIPS APM scoring standard, which is designed to reduce reporting burden for participants in certain APMs by minimizing the need for duplicative data submissions under both MIPS and their respective APMs. CMS sought to ensure that eligible clinicians in APM Entities who participate in certain types of APMs that assess their participation on quality and cost are assessed as consistently as possible.

We are supportive of MIPS APMs as a step in the continuum from MIPS to Advanced APMs. CMS should take actions that are needed to make it as accessible as possible for physicians to transition from MIPS, to MIPS APMs, to Advanced APMs. Considering MIPS APMs as a stepping stone between MIPS and Advanced APMs is one way to create an incentive for physicians to move toward Advanced APMs, which is one of the clear goals of MACRA. We urge CMS to view MIPS APMs as a lower risk option for physicians to test out APM participation. The business model transformation from MIPS to Advanced APMs for most practices that are not affiliated with large institutional providers will be a significant challenge. While we continue to be concerned about the lack of participation options available to surgeons, one way for physicians to gain experience with APMs and move closer to full Advanced APM participation is to participate in a MIPS APM. We also encourage CMS to consider as MIPS APMs all models that are recommended by the Physician-Focused Payment Model Technical Advisory Committee (PTAC). Such models have shown that they meet the PTAC criteria and have been recommended for implementation by the Secretary as Advanced APMs, so approving them as MIPS APMs would be a logical step in the continuum.

We also urge CMS to consider MIPS APMs as a safety net for those who attempt to participate in any Advanced APM, but do not meet the QP or Partial QP Threshold. Ideally, this would encourage physicians to attempt to participate in Advanced APMs and provide them with a benefit for attempting even if they do not clear the payment amount or patient count thresholds for QP or Partial QP status. Under the current policy, one result is that physicians who attempt to participate in MIPS APMs compared to some Advanced APMs are treated differently in certain cases. For example, although most Advanced APMs are also considered MIPS APMs, if a physician attempts to participate in the Comprehensive Care for Joint Replacement (CJR) Track 1 Advanced APM and does not succeed, the clinician would not then be eligible for scoring under the MIPS APM Scoring Standard. This is because the CJR, while an Advanced APM, is not considered a MIPS APM. Therefore, those surgeons

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who become participants in the CJR Advanced APM would not have the safety net that other Advanced APM participants have when they are not able to meet the QP or Partial QP thresholds.

We ask that CMS consider the CJR Advanced APM model to be a MIPS APM model as well. In addition to the safety net issue described above, having the CJR also qualify as a MIPS APM would support the concept of MIPS APMs as a step in the continuum toward Advanced APMs. In addition, now that CMS is proposing facility-based scoring under MIPS there is a way for clinicians participating in the CJR and other future hospital-based episodes to be assessed based on the facilities that they are aligned with. We recommend that CMS consider specifying that for CJR Track 1, Affiliated Practitioners not reaching the QP or Partial QP thresholds should be able to use the hospital cost/quality data, analogous to the facility-based scoring under MIPS in order to be scored as a MIPS APM. Using hospital quality measures would also help introduce more robust quality measures for those participating in the CJR.

Calculating MIPS APM Performance Category Scores

QUALITY PERFORMANCE CATEGORY

CMS proposes a QPP 2018 performance year quality scoring methodology for Other MIPS APMs and describes the scoring methodology for quality improvement for Other MIPS APMs as applicable. Other MIPS APMs are MIPS APMs that do not require reporting through the CMS Web Interface. The CMS Web Interface is used to generate a MIPS APM quality performance category score for participants who submit quality data exclusively through that reporting mechanism. CMS proposes that quality will be 50 percent of the performance score, ACI will be 30 percent, IA will be 20 percent, and cost set at 0.

For purposes of Other MIPS APM scoring, CMS will score only measures that are:

- (1) tied to payment as described under the terms of the APM;
- (2) are available for scoring near the close of the MIPS submission period;
- (3) have a minimum of 20 cases available for reporting; and
- (4) have an available benchmark.

We ask that CMS view the Other MIPS APM quality measure requirement through the lens of how to support drawing physicians into APM models. Transitioning from MIPS to Advanced APMs is complex. The burden of transforming an existing business model into one that supports a new payment model is difficult and risky for most practices. We ask that CMS remove

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unnecessary barriers for those clinicians who are considering exploring MIPS APMs or Advanced APMs.

We are most concerned about the fourth measure requirement, that the MIPS APM measures have an available performance benchmark. **To allow for flexibility as models are being developed and implemented in this early stage of the QPP, we ask that CMS consider measures to qualify for the purpose of MIPS APMs scoring as long as at least one of the measures included in the model has performance indicator benchmarks and also allows for the conditional inclusion of measures that might develop a benchmark during the performance period.** In this year's proposed rule, CMS published the list of measures that would be finalized for 2018 under these criteria. We ask CMS to verify that the criteria require that a measure be "benchmarkable" as opposed to having a benchmark at the time of the final rule publication. Requiring all measures to have performance benchmarks at the time of the publication of the final rule in the previous calendar year will be too restrictive and will limit the use of some models that can be used to smooth the transition from MIPS to Advanced APMs. Further, our recommended approach is consistent with treatment of quality measures under MIPS, for which CMS allows establishment of benchmarks for new measures based on the performance period if benchmarks from a prior period are not available. Requiring that all MIPS APM measures have an available performance benchmark is too much too soon, given that CMS is still refining the scoring standard for the quality performance category.

MIPS FINAL SCORE METHODOLOGY

Although we do not yet have the data to assess the MIPS success rate for surgeons in the 2017 performance period, there is consensus in the feedback we have received from our members that the MIPS program is extremely burdensome, overly complex, remains siloed, is costly to implement and ultimately takes away from patient care. Given the efforts to reduce regulatory burden, we strongly encourage stability and simplicity in the 2018 performance year.

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Converting Measures and Activities into Performance Category Scores

Policies That Apply Across Multiple Performance Categories

SCORING FLEXIBILITY FOR ICD-10 MEASURE SPECIFICATION CHANGES DURING THE PERFORMANCE PERIOD

Both the Quality and Cost performance categories include measures that include ICD-10-CM/PCS (“ICD-10”) codes. ICD-10 coding updates are effective October 1, through September 30th. For measures considered significantly impacted by ICD-10 updates—which may render the measures no longer comparable to the historical benchmark—CMS proposes to assess performance based on the first 9 months of the 12-month performance period, because the indicated performance for the last quarter could be affected by the coding changes rather than actual differences in performance, as a result of the annual update cycle.

CMS determination as to whether a measure is significantly impacted by ICD-10 coding changes includes the following factors: a more than 10 percent change in codes in the measure numerator, denominator, exclusions, and exceptions; guideline changes or new products or procedures reflected in ICD-10 code changes; and feedback on a measure received from measure developers and stewards. **ACS supports the proposal to assess performance based on the first 9 months of data to align with annual ICD-10 updates. However, we seek clarity on whether stakeholders will have an opportunity to respond to measure changes. We believe that this should be a formalized process published in a notice of proposed rulemaking (NPRM).**

Scoring the Quality Performance Category for Data Submission via Claims, Data Submissions via EHR, Third-Party Data Submission Options, CMS Web Interface, and Administrative Claims

QUALITY MEASURE BENCHMARKS

CMS explains that for the 2020 payment year, there will be a decrease in the number of providers who will contribute to the MIPS benchmark because of the low-volume exclusion, which will be approximately two-thirds of clinicians, or more than 900,000 providers. CMS questions how this may impact MIPS benchmarks and solicits feedback on whether to broaden the criteria for creating MIPS benchmarks to include PQRS as well as additional data from MIPS such as voluntary reporters. ACS greatly appreciates that CMS recognizes the possible impact the low volume threshold could have on MIPS

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benchmarks and commends CMS for seeking public feedback on this issue. **However, ACS does not support the proposal to include additional data in the MIPS benchmark because simply adding additional data could introduce bias and will not result in more accurate benchmarks.** PQRS is a pay-for-reporting program with very different reporting requirements compared to the MIPS pay-for-performance program, and therefore PQRS data is not generalizable to the MIPS program. For example, PQRS Measure Groups only required a minimum of 20 patients over a 12-month reporting period which is likely a bias sample of a provider's patients. Some providers may have been motivated to report their twenty best cases since CMS didn't not have reporting parameters that would have prevented them to do otherwise.

Additionally, while CMS does not propose any change to policies related to benchmarks by practice size for the 2020 payment year, the Agency seeks comment on methods by which CMS could stratify benchmarks while maintaining reliability and stability of future benchmarks. CMS seeks comment on specific criteria to consider for stratifying benchmarks by specialty or place of service. **ACS supports stratification for purposes of quality improvement and risk adjustment for determining payment. Stratified results also demonstrate to CMS where more resources are needed to overcome the challenges vulnerable populations face from their socioeconomic status. ACS does not support comparing all physicians "en masse."** A family practitioner should not be compared to a general surgeon nor should all surgeons necessarily be compared. To this end, ACS supports efforts to explore how to appropriately compare surgeons within a particular surgical specialty. We welcome working with CMS to address these challenges and for appropriately translating such scores into reasonable payment adjustments.

ACS also acknowledges that given the low volume threshold for the 2020 payment year, the consideration to stratify will likely further complicate the issues raised with the low volume threshold. However, first and foremost, the MIPS measurement systems needs rigor in common data aggregation, common data analytics, and reporting. CMS should closely analyze the impact of stratification as it relates to the low volume threshold and the overall impact on reliability and validity.

Other Quality Benchmark Concerns

MACRA requires that, starting in 2019, the MIPS performance threshold be set at the mean or median of the composite performance score, thereby penalizing approximately half of all Part B providers. Our concern with this policy is that the current CMS solutions to measurement science are not advanced enough to accurately inform patients and providers. In fact, **the current measure results**

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misinform patients and providers because of a lack of reliable and valid information, while collecting data across multiple disparate data systems.

As we previously discussed, one solution proposed by CMS is harmonization of measure definitions, but accurate measurement requires more than common definitions. This was demonstrated when ACS harmonized the ACS NSQIP SSI measure with the Centers for Disease Control and Prevention CDC NHSN SSI measure when measuring in the same facilities. After harmonization, results showed that NSQIP participants had higher SSI rates compared to the CDC NHSN registry. Through further study, ACS found that this discrepancy was not because NSQIP participants had poorer surgical outcomes, instead, the discrepancy was due to the lack of rigor used to track patients and collect data for use in the NHSN registry when compared to NSQIP.¹⁴

Therefore, the MIPS measurement systems needs rigor in common data aggregation, common data analytics, and reporting. As we previously cited, the Society for Thoracic Surgery (STS) National Database is an example of consistency across measurement because one data system exists for a small number of operations, allowing for a single method for data aggregation, analytics, and reporting. If STS had multiple vendors collecting and analyzing data, results would not be as useful even after large expansive efforts. Another challenge is that MIPS measures lack meaning for surgeons and surgical patients—many are “singleton” which does not give a comprehensive picture of care across an episode.

As a solution, ACS is developing a comprehensive measure framework inclusive of high value process measures across an episode of care coupled with complementary patient reported outcome (PRO) and patient reported experience (PRE) measures to measure surgeons across the phases of surgical care in alignment with a patient’s clinical flow, including: preoperative preparation, perioperative final prep, intraoperative care, postoperative care and post discharge. Each of these phases involves key processes, critical care coordination to primary care physicians and anesthesia, as well as the technical side of surgical care that relates to safety, outcomes and avoidable harms. This framework, which broadly applies to surgical care for cross-cutting comparisons, was constructed to allow for more detailed, procedure-specific metrics to be added when necessary, and it fits well for use in an APM. We propose solutions which provide consistent reliable methods for data definitions, methods of aggregation and normalization and methods for reporting to the payer and the public.

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¹⁴ Ju, M. H., Ko, C. Y., Hall, B. L., Bosk, C. L., Bilimoria, K. Y., & Wick, E. C. (2015). A comparison of 2 surgical site infection monitoring systems. *JAMA surgery*, 150(1), 51-57.



We welcome working with HHS to address some of the issues outlined with the current set of circumstances in the MIPS program, such as identifying ways to normalize physician data for comparison in MIPS and how to best compare surgeons given the limitations.

CASE MINIMUM REQUIREMENTS AND MEASURE RELIABILITY AND VALIDITY

CMS does not propose any changes to its case minimum policies that require at least 20 cases for all quality measures, except the hospital readmissions measure, which requires at least 200 cases and only applies to groups of 16 or more clinicians that meet the case minimum requirement. For the 2019 payment year, CMS finalized the following two classes of measures:

Class 1: Measures that can be scored based on performance. Measures that were submitted or calculated that met the following criteria: The measure has a benchmark, at least 20 cases; and meets the data completeness standard (generally 50 percent). These measures would receive 3 to 10 points based on performance compared to the benchmark.

Class 2: Measures that cannot be scored based on performance. Measures that were submitted, but fail to meet one of the Class 1 criteria. The measure either does not have a benchmark, does not have at least 20 cases, or does not meet data completeness criteria. These measures would receive 3 points.

CMS proposes to revise the Class 2 measures to only include measures that cannot be scored based on performance because they do not have a benchmark and do not have at least 20 cases. Regarding measures that do not meet the data completeness criteria, CMS proposes to create Class 3 measures. Class 3 measures would only earn 1 point, unless the measure is submitted by a small practice with 15 or fewer clinicians—those small practices would receive 3 points. **ACS approves the concept of the Class 3 measure, contingent on a 90-day minimum reporting period for the Quality performance category. We think it is reasonable that providers be awarded only 1 point if they cannot meet the data completeness requirement for 90-day reporting period. We do not support this proposal if the reporting period is finalized for longer than a 90-day period.**

INCENTIVES TO USE CEHRT TO SUPPORT QUALITY PERFORMANCE CATEGORY SUBMISSIONS

CMS seeks comment on how to encourage the use of CEHRT in quality measurement. CMS currently awards 1 bonus point for each measure that is

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submitted with end-to-end electronic reporting with a cap at 10% of the denominator of the quality performance category performance score, for the first two years of the program. ACS believes that CMS should provide incentives on the inclusion of meaningful episode-based measures in a clinical data registry.

Scoring the Cost Performance Category

CMS proposes policies to incorporate improvement into the calculation of the Quality and Cost performance categories' percent score and proposes data sufficiency standards under which data would generally be available to measure improvement. While we appreciate CMS' effort to provide credit for improvement achieved under both categories, we have concerns that these proposed policies seek to build on an already-unstable performance measurement foundation, thereby limiting the value of any resulting information they might otherwise provide.

To begin, the concept of improvement assumes that measures used in MIPS are valid and reliable. As discussed above, however, ACS has demonstrated that MIPS measures – which largely do not have complete and accurate benchmarks – do not accurately represent a clinician's care. **Given our concerns with existing measures and the current state of quality and cost measurement under MIPS, we do not support this proposal because we believe that the available data are insufficient to measure improvement in a valid and reliable manner.**

Layering on the measurement of improvement, which comes with its own challenges, further complicates our ability to understand and assess clinician performance. For example, we believe CMS' proposed policies could create incentives to cherry-pick patients and treat those who would result in the greatest improvement. At the same time, CMS assumes that a provider's patient population is stable and does not consider the potential for clinicians' patient populations to change from one year to the next, for example if a clinician moves from one practice to another. With respect to the Cost performance category it would be premature to assess improvement given the absence of proposed episode-based measures for performance year 2018; such measures are needed to help ensure fairer comparisons and provide more relevant feedback to clinicians than the Total Per Capita Cost and MSPB measures that would remain, but only after they are determined to be valid and reliable.

Given the above, before scoring improvement, we urge CMS to address underlying methodological issues with performance measurement under

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both the quality and cost performance categories, including related to reliability and validity of measures, risk adjustment, and the availability of measures that meaningfully assess care provided by clinicians who practice across all settings and specialties. A solid performance measurement foundation will allow CMS to address challenges regarding implementation of improvement scoring such as those noted above in a more targeted manner. We have provided specific recommendations on how to improve measurement science in both the Quality and Cost sections in this letter.

Facility-Based Measures Scoring Option for the 2020 MIPS Payment Year for the Quality and Cost Performance Categories

CMS proposes to implement facility-based measures for assessment under the MIPS quality and cost performance categories starting with performance year 2018. Specifically, CMS proposes that the quality and cost measures that may be used for facility-based measurement are those adopted under the value-based purchasing program of a specified facility program for a specified year. For the 2020 MIPS payment year, CMS proposes to limit facility-based measurement to the measures used in the inpatient hospital performance under the FY 2019 Hospital Value-Based Purchasing (HVBP) Program. In developing these proposals, CMS considered whether to include the entire set of Hospital VBP Program measures for the purposes of facility-based measurement under MIPS or attempt to differentiate those which may be more influenced by clinicians' contribution to quality performance than others, but opted for the former based on the belief that attempting to differentiate measures undermines the team-based approach of facility-based measurement. CMS does not propose any additional improvement scoring for facility-based measurement for either the quality or cost performance categories, and CMS does not propose to provide bonus points for high-priority measures or end-to-end electronic reporting.

CMS proposes to allow "facility-based" MIPS eligible clinicians or groups to be eligible for facility-based measurement, with MIPS eligible clinicians being considered facility-based if 75 percent or more of their covered professional services are furnished in sites of service identified by place of service (POS) code 21, for inpatient hospital, or POS code 23, for emergency room. CMS also seeks comment on whether POS code 22 should be included in determining if a clinician is facility-based. CMS proposes that a facility-based group is a group in which 75 percent or more of the MIPS eligible clinician NPIs billing under the group's TIN are eligible for facility-based measurement as individuals.

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CMS also proposes or solicits comment on several proposals and potential alternatives that could provide an advantage to MIPS eligible clinicians and groups eligible for facility-based measurement, including: providing advance notice to facility-based clinicians of potential facility-based scores before the data submission period; assigning a “higher of” score based on performance under facility-based measurement versus standard assessment under the quality and cost performance categories, without requiring active election of facility-based measurement; and for individuals and groups who elect facility-based measurement but submit quality data through another MIPS mechanism, using the higher of the two scores for the quality performance category and basing the score of the cost performance category on the same method.

Overall, while we strongly support the use of facility-based measures under MIPS in concept, we have several concerns with CMS’ approach to facility-based measurement. Specifically, we believe any assessment under MIPS should be reflective of the care clinicians provide and should drive quality improvement. Additionally, facility-based measurement should still allow for meaningful measurement and comparison across clinicians and groups participating under MIPS.

We do not believe CMS’ proposal, which focuses on overall assessment of hospitals under the HVBP Program, sufficiently achieves these goals. While we recognize and appreciate that the set of HVBP measures, as a whole, are more targeted towards the care that certain surgical specialists provide compared to the measures available via Web Interface reporting, many of the measures are not relevant to various surgical specialties, and the performance of many specialists and subspecialists would not be incorporated into assessment under the MIPS program if they elected to participate in facility-based measurement under the CMS proposal. Instead, these clinicians would be assigned Quality and Cost performance category scores based on their hospitals’ performance on measures that do not reflect their own contributions. Thus, we have concerns that this proposal would not sufficiently drive targeted quality improvement. Rather, it would create unnecessary complexity, in essence subdividing participation under MIPS into multiple separate programs based on place-of-service with separate benchmarks and performance requirements. This, in turn would undermine CMS’ ability to meaningfully compare and rank practices’ performance for the purposes of determining payment adjustments under MIPS.

We believe that CMS could largely address these concerns by implementing facility-based measurement using facility-level measures from nationally validated, risk-adjusted, outcome-based registries with a demonstrated ability to drive improvement with a targeted approach, such

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as the ACS NSQIP. The use of such registries would incorporate valid and reliable facility-based measures that are targeted enough to reflect the performance of clinicians, while also varied enough to apply across a wide range of specialties and sites of service, thereby driving quality improvement among participating clinicians. Additionally, measures from such registries could readily be incorporated into the existing MIPS quality scoring methodology, allowing for meaningful measurement and comparison across MIPS eligible clinicians. Though we recognize that NSQIP and other similar registry measures are not regularly used in other payment systems, we would strongly encourage CMS to allow for flexibility in reporting requirements and measure selection, such as the data submission requirement, so that clinicians can report relevant facility-based measures in the MIPS program. Again, we are not opposed to the incorporation of facility-based measures in MIPS, but rather the limited manner in which CMS proposes to do so for 2018. **ACS welcomes the opportunity to work with CMS on how the methodologies used to determine a facility's performance can translate into a valid and reliable measure for facility-based measurement in the MIPS program.**

With respect to CMS' proposal to use HVBP Program performance under the Cost performance category, in addition to the Quality performance category, we believe that assessment under the Cost category should focus on episode-based risk-adjusted measures that align with measures used for facility-based reporting in the Quality performance category. The HVBP Program does not include such measures, instead only relying on the MSPB measure to assess resource use. As noted above, episode-based risk-adjusted measures would provide a fairer way to compare clinicians on measures that are relevant to the care they provide. As such, they should be built into any mechanism to assess clinicians on resource use, including for facility-based measurement.

In conclusion, we disagree that CMS should adopt a full set of measures from existing programs, rather than identify those measures that are most applicable and relevant to MIPS eligible clinicians. We believe that facility-based measures like those included in NSQIP maintain accountability for team-based care while better reflecting clinician performance and promoting quality improvement. We also believe that CMS should not be limited to measures used under pay-for-performance programs, particularly if – as we envision – individual facility-level measures that are reflective of clinician performance are folded into the MIPS pay-for-performance structure.

Should CMS move forward with implementation of the facility-based measurement proposals largely unchanged, we support CMS' proposals for determining how a MIPS eligible clinician or group would be facility-based. We also support CMS' proposal to not include improvement scoring or bonus points under the facility-

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based measurement proposal. We do not agree, however, with CMS' proposals or potential alternatives that would provide an automatic scoring advantage for those facility-based MIPS eligible clinicians and groups who are eligible for facility-based measurement. For example, **we recommend that CMS require MIPS eligible clinicians to elect to be assessed under facility-based measurement, as CMS proposes. For those who make such an election, CMS should apply the Quality and Cost performance category scores calculated under facility-based measurement, rather than take a "higher of" approach to scoring.** We are concerned that policies that automatically allow for a competitive advantage for a subset of MIPS eligible clinicians would be inequitable and would serve to reduce incentives for quality improvement.

In the future, we also encourage CMS to consider the inclusion of surgical ASC measures for use in the MIPS program, as the majority of surgical procedures are performed in the ASC setting. This would likely require CMS to define a separate criterion for how it would make these determinations. ACS welcomes working with CMS to determine how to best measure care provided in the ASC.

CONSIDERATIONS FOR SOCIAL RISK

CMS continues to seek public comment on whether it should account for social risk factors in the MIPS program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors in MIPS. Examples of methods provided by CMS include: adjustment of MIPS eligible clinician scores (for example, stratifying the scores of MIPS eligible clinicians based on the proportion of their patients who are dual eligible); confidential reporting of stratified measure rates to MIPS eligible clinicians; public reporting of stratified measure results; risk adjustment of a particular measure as appropriate based on data and evidence; and redesigning payment incentives (for instance, rewarding improvement for clinicians caring for patients with social risk factors or incentivizing clinicians to achieve health equity). CMS also seeks public comment on which social risk factors might be most appropriate for stratifying measure scores and/or potential risk adjustment of a particular measure.

The ACS applauds CMS on its responsiveness to recent findings examining the adjustment of social risk factors, including the concern regarding the potential impact the lack of social risk factor adjustment. ACS has long advocated for further study in this area. ACS believes there is a critical need for even further study in this area. The initial findings from NQF indicate they have only begun understanding this topic and further

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research is necessary.¹⁵ Recent findings from ASPE indicate the work they have done to date is only the beginning of a body of “necessary work around fair and accurate quality measurement in the context of Medicare’s increasing use of value-based purchasing programs.”¹⁶ ASPE notes further research will be done on socioeconomic status (SES) factors not found in Medicare data, and recommends future research could focus on functional status or frailty on the relationship between SES and a provider’s performance, as well as care innovations associated with the with good health outcomes in this population.¹⁷

There is also work to be done to specifically identify which factors have an impact on vulnerable populations. For example, CMS solicits a response on whether MIPS scores should be stratified based on the portion of their patients who have dual eligible status in Medicare. We would argue that this adjustment may be too blunt, and we may be misinforming the public and incorrectly measuring providers—we need more information regarding which specific factors result in higher spending and/or poorer health care outcomes. Most of the research conducted to date only analyzes data found in Medicare data which has limited information on social factors. Much of the feedback from NQF’s measure developers and other stakeholders expressed the concern that we need better patient-level and community-level data sources for SES, and that greater standardization of SES variables and methods to improve testing measures for SES risk adjustment. The National Academy of Medicine report also indicated the need for research on additional SES factors.¹⁸

Other research has demonstrated that racial and economic disparities fail to explain the poor health outcomes across the U.S., and when comparing our health system to other industrialized nations, U.S falls short in our investment in social services to support the broader social determinants of health.¹⁹ This is further supported in the ASPE report which found that providers who cared for patients with lower SES performed worse in quality measurement, and those

¹⁵ Evaluation of the NQF Trial Period for Risk Adjustment for Social Risk Factors (Rep.). (2017, July 18). Retrieved file:///I:/Quality/Risk%20Adjustment/ses_trial_final_report.pdf.

¹⁶ REPORT TO CONGRESS: SOCIAL RISK FACTORS AND PERFORMANCE UNDER MEDICARE’S VALUE-BASED PURCHASING PROGRAMS (Rep.). (2016, December 21). Retrieved <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs>

¹⁷ REPORT TO CONGRESS: SOCIAL RISK FACTORS AND PERFORMANCE UNDER MEDICARE’S VALUE-BASED PURCHASING PROGRAMS (Rep.). (2016, December 21). Retrieved <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs>

¹⁸ National Academies of Sciences, Engineering, and Medicine. (2016). Accounting for Social Risk Factors in Medicare Payment: Criteria, Factors, and Methods. National Academies Press.

¹⁹ Bradley, E., & Taylor, L. (2015). The American health care paradox: Why spending more is getting us less. PublicAffairs.

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differences persisted even after adjusting the measures. **ACS strongly encourages CMS to look at how social determinants of health affect Medicare beneficiaries and how SES can be incorporated into measurement. ACS also recommends the Secretary encourage CMS to work with other HHS agencies to prioritize research efforts to examine the broader social determinants of health, as well as ASPE's and NQF's recommendations.**

In general, ACS supports SES risk adjustment for measures used in accountability applications (e.g., public reporting and pay-for-performance) on a case-by-case basis. It is established that without the use of appropriate risk adjustment for certain measures, clinical outcomes will be less reliable due to SES confounding variables. Closely evaluating the appropriate factors for SES confounding variables will lead to a deeper understanding of the relationship between these variables and clinical outcomes. Until there are further findings on the appropriate application of risk adjustment, including which factors to include in SES adjustment and further study on social support services, the ACS supports the following methodology, when appropriate:

- For purposes of **accountability** (e.g., public reporting, pay-for-performance), SES factors should be included in **risk adjustment** on a case-by case basis and when they demonstrate a conceptual and empirical basis for adjustment.²⁰
- Stratified results are also important to consider because they can demonstrate to CMS where more resources are needed to overcome the challenges vulnerable populations face from their SES.

By providing both the risk adjusted and the stratified results, CMS can avoid unfairly penalizing providers with a more vulnerable patient population, while also allowing providers to drill down on relevant SES factors to improve the outcomes of disadvantaged patients. Additionally, as discussed above, to have reliable benchmarks ACS proposes solutions that provide consistent reliable methods for data definitions, methods of aggregation and normalization, and methods for reporting to the payer and the public. This methodology must be robust, and agreed upon across stakeholders.

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²⁰ Evaluation of the NQF Trial Period for Risk Adjustment for Social Risk Factors (Rep.). (2017, July 18). Retrieved file:///I:/Quality/Risk%20Adjustment/ses_trial_final_report.pdf.



COMPLEX PATIENT BONUS

As a short-term strategy for the QPP to address the issue of patient complexity, including stratification or risk adjustment for SES factors, CMS proposes a small bonus for providers with “complex patients.” CMS proposes to calculate an average CMS Hierarchical Condition Categories (HCC) risk score, using the model adopted for Medicare Advantage risk adjustment purposes, for each MIPS eligible clinician or group, and to use that average HCC risk score as the complex patient bonus. CMS would add this amount (the size of the average HCC risk score) to the final score for the 2020 MIPS payment year for MIPS eligible clinicians that submit data for at least one performance category. CMS proposes that if a calculation results in greater than 100 points, then the final score would be capped at 100 points. CMS proposes that the complex patient bonus cannot exceed 3 points. As an alternative CMS proposes to use a formula based on the proportion of a MIPS eligible clinician’s dual eligible patients.

Although we greatly appreciate CMS’ effort to immediately address the issue of how different patient characteristics can impact scores in the QPP program, we have several concerns with the proposal and possible solutions to those concerns. To start, we do not understand why CMS is looking at either/or choice between using the HCC adjustment or dual eligible patients. Although we are familiar with data that demonstrates that the dual eligible population has worse outcomes and is the most costly to the health care system, if we only look at the dual eligible population we would be missing a large number of complex patients in the Medicare program. In other words, just looking at dual eligible is too narrow. Since the HCC risk adjustment looks at clinical comorbidities, we encourage CMS to use both methodologies so that we will also identify those with complex clinical conditions. Additionally, we think it is important to consider the cost of caring for these patients and ask CMS to adjust for those differences in calculating the Cost performance category for future years.

We also encourage CMS to increase the complex patient bonus to at least up to 5 points, which is equivalent to the small practice bonus. Three points is simply not enough to incentivize behavior change and for providers to feel like their score will be fairly adjusted for when they choose to treat complex patients. **In summary, we believe that CMS should consider both the dual eligible and HCC adjustment, to raise the bonus to at least up to 5 points and to consider how CMS can account for the higher cost of care for the most complex patients.** Again, please note that we are commenting on these proposals as a short term-strategy, and believe it is critical to make investments in studying SES factors for inclusion in adjusting a provider’s MIPS score.

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SMALL PRACTICE BONUS FOR THE 2020 MIPS PAYMENT YEAR

The ACS thanks CMS for the multiple initiatives included in the 2018 proposed rule designed to engage and accommodate small and rural practices. Perhaps the most significant example of such is the 5-point bonus provided for small practice groups, Virtual Groups, and APM entities consisting of 15 or fewer clinicians that submit data for at least one performance category. Again, ACS would encourage CMS to continue, to the greatest extent feasible, these substantive policies that take into account those in small and rural practices.

Final Score Calculation & Final Score Performance Category Weights

CMS explains that it proposes to build on MIPS final score policies from the first transition year of MIPS. CMS has several new proposals that will be used to determine a provider's final score, including:

- For quality, a change in the number of the achievement points for measures that fail to meet data completeness with exceptions for small practices;
- An improvement scoring methodology that rewards providers who improve their quality and cost scores;
- A new facility-based option that allows facility-based providers to be scored based on the performance of their facility;
- The ability to earn bonus points for providers who treat complex patients, and
- Various pathways for providers to earn a neutral adjustment, similar to the first transition year.

Although we greatly appreciate CMS' efforts in allowing flexibility for the various types of MIPS eligible clinicians, including those who treat complex patients, have small practices, and those who are facility based, the CMS goal for the QPP seems very unclear. As discussed in our general comments, **ACS seeks clarity on what direction CMS is headed regarding the Agency's commitment to delivering the promise of MACRA. The current proposals increased complexity through multiple disparate data systems with competing measures and methodologies.** While this may provide flexibility for practices in the short term, it does not address the need to increase rigor and therefore will result in a provider's performance being judged inaccurately, with erroneous payments and misclassified performance in public reports.

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MIPS PAYMENT ADJUSTMENTS

Establishing the Performance Threshold

For the first transition year of MIPS, CMS set the performance threshold at 3 points which allowed providers to test out the program and avoid a penalty by submitting minimal data. Any provider who meets the performance threshold avoids a penalty in the MIPS program and receives a neutral adjustment. For the second performance year of MIPS, CMS proposes to set the performance threshold at 15 points. This will raise the requirements, and providers will have to increase their MIPS participation to avoid a penalty. For example, the performance threshold could be met by full participation in the quality performance category, where providers could earn at least a quality performance category percent score of 30 percent by meeting data completeness for submitting all required measures. CMS also expresses concern that the step from a 15-point threshold in the 2018 performance to a score based on the mean or median in 2019 may be very steep for some providers and seeks comment for setting a lower or higher threshold for the 2018 performance year.

ACS seeks clarity on how CMS plans to determine the mean or median for the 2019 performance year. We believe that the statute provides a lot of flexibility for how CMS determines the mean or median, yet we have no information on how CMS may use the 2018 performance data to determine the 2019 threshold. For example, will bonus points be calculated as part of the mean or median? What does the spread of physicians look like if CMS chose either the median or mean? We imagine it is possible that if many providers simply met the performance threshold, the median could be close to the 2018 performance threshold. Again, it is difficult to comment on how proposals to the 2018 performance threshold could impact the 2019 performance year, and therefore we seek clarity from CMS. If CMS has difficulty in determining whether to use the mean or median, ACS encourages CMS to choose the lower benchmark of the two. As discussed earlier, the lack of information goes back to the point that it is critical for CMS develop a roadmap for implementation of the QPP.

Without further clarity from CMS, we advocate for stability and simplicity in the MIPS program while avoiding overcomplicating and burdening providers. As discussed throughout this comment letter, it is critical that CMS and stakeholders work on improving program alignment, advancing health IT, and increasing reliability and validity—which includes allowing for a single method for data aggregation, analytics, and reporting. Until many of these factors are addressed, ACS supports holding providers to a minimum standard because the current program misclassifies care provided by MIPS eligible

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clinicians while detracting from patient care due to administrative burdens, and therefore does not advance the quality of care. To this end, we also strongly urge CMS to conduct an assessment on the time needed to participate successfully in QPP, including education required and additional resources, as well as if this yields a benefit to patients.

REVIEW AND CORRECTION OF MIPS FINAL SCORE

Feedback and Information to Improve Performance

CMS is currently developing systems needed for performance feedback in MIPS and has begun to develop real-time feedback on data submission and scoring, where technically feasible. CMS explains that they plan to continue to engage in user research with front-line clinicians to ensure CMS is providing the performance feedback data in a user-friendly format, and that CMS is including data most relevant to clinicians.

ACS greatly appreciates CMS responding to our past comments which have advocated for real-time performance feedback. We believe the goal of performance feedback should be an interactive dashboard for providers with real-time information to let them know the targets for quality measurement, improvement and cost, as well as the status of their QPP participation at any point of time. This will require one standard dashboard per physician or one dashboard per payer which illustrates what is being measured and how it will be analyzed. This concept goes back to the necessity of open source data standards and interoperability, discussed in detail in our general comments and ACI section. ACS strongly urges CMS to better engage physician organizations to develop the best format for performance feedback. Quality and Resource Use Reports (QRURs) have historically been incredibly hard to access and understand, rendering generally useless for surgery. We recommend a formalized process for developing the interface, such as a committee or expert panel. CMS could possibly provide IA credit for committee members who help with the performance feedback design.

CMS also notes they are working on an API to allow third-party vendors to access the same data that CMS uses to provide confidential feedback to providers and so providers can get all of their feedback via the same third-party mechanism. ACS supports this direction, and emphasizes the importance of including a feedback loop and the ability to track not just traditional measures, but also patient reported outcomes.

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THIRD-PARTY DATA SUBMISSION

In the Third-Party Data Submission section, CMS asks a series of questions to solicit input to further advance the role of third-party intermediaries and to reduce clinician burden by enabling a streamlined reporting and feedback system. One topic that CMS asks about is longitudinal data:

- Should there be additional refinements to evaluate third parties that can deliver longitudinal information?
- Should there be a special designation for registries that convey the availability of longitudinal data?

While the ACS agrees with the value of capturing longitudinal data, we remind CMS of the barriers that currently exist in regard to tracking a patient over time. These include patients that move to different geographic locations or seek care from other providers who might not have systems that communicate with the original clinician. For example, a provider could get bariatric surgery in Boston but then go home to Virginia. The long term follow up would happen across many providers in Virginia. This is hard to track in a registry because most patients get their care in multiple places. **Until we have a patient identifier that could be used by all payers and all systems to track and map patients over time and over providers, registries should not be awarded special status for their ability to track longitudinal data.**

Registries, by their very nature, strive to track longitudinal data for as long as possible. We do not believe CMS should distinguish between registries that are able to track patients longer than others since this is dependent on a variety of factors such as the patient, the condition/procedure/specialty, and other external factors outside of the control of the registry.

Qualified Clinical Data Registries (QCDRs)

Self-Nomination Period

CMS previously finalized that the self-nomination period for the 2018 performance period and for future years of the program would be from September 1 of the year prior to the applicable performance period until November 1 of the same year (i.e., September 1, 2017 through November 1, 2017 for the 2018 performance period). Recognizing that some QCDRs have no changes to the measure and/or activity inventory from year to year, CMS proposes, beginning with the 2019 performance period, a simplified process in which existing QCDRs in good standing may continue their participation in MIPS, by attesting that the QCDR's approved data validation plan, cost, measures, activities, services, and performance categories offered in the

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previous year's performance period of MIPS have minimal or no changes and will be used for the upcoming performance period. In addition, the existing QCDRs may decide to make minimal changes to their approved self-nomination application from the previous year, which would be submitted by the QCDR for CMS review and approval by the close of the self-nomination period. These may include limited changes to their performance categories, adding or removing MIPS quality measures, and adding or updating existing services and/or cost information. Existing QCDRs in good standing may also submit for CMS review and approval, substantive changes to measure specifications for existing QCDR measures that were approved the previous year, or submit new QCDR measures for CMS review and approval without having to complete the entire self-nomination application process. CMS also clarifies that substantive changes to existing QCDR measure specifications or any new QCDR measures would have to be submitted for CMS review and approval by the close of the self-nomination period.

The ACS very much appreciates CMS's effort to ease the administrative burden of QCDRs in good standing. This would mean that the QCDR would spend less time completing the entire self-nomination form each year. While we support a more streamlined process, we still have concerns about this proposal. For one, we are very concerned and have questions about the previously finalized timeline. Although an earlier self-nomination deadline will ensure that clinicians have information about available QCDR options prior to or closer to the start of the performance period, it does not leave vendors with much time to evaluate the current performance period and to make adjustments to measures, methodologies, and data collection processes in time for the next year. For example, ACS will not have a full year's worth of 2017 data (and maybe not even a full 6 months of data) before having to start thinking about changes for 2018. Also, if ACS submits the same measures for 2018 by the November 1, 2017 deadline, what if CMS has feedback or rejects some measures (since some of our measures were provisionally approved for 2017)? Would we be able to submit new measures, if needed, and by when?

We also do not believe this policy proposal sufficiently addresses what is currently one of the most problematic aspects of the QCDR self-nomination process, which is the disorganized, unpredictable, and time-consuming manner in which QCDR measures are reviewed by CMS. ACS's experience with the 2017 QCDR measure review period was extremely frustrating as a result of inconsistent feedback and impractical timelines, and a lack of rationale for rejected measures. We strongly urge CMS to develop a standardized process for reviewing QCDR measures. This process should include structured timeframes for an initial review period, an appeals process, and a final review, as well as mechanisms to ensure transparency and predictability. One way to

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work towards these goals would be for CMS to assign a coordinator for each QCDR and create an official database containing decisions on measures to ensure there are no conflicting messages.

While multiple fixes are necessary, one way to maximize stability and predictability, while minimizing complexity would be to offer multi-year approval of QCDR measures. We believe QCDRs should be allowed to make minor modifications to measures under this multi-year approval process based on updated guidelines, evidence or measure methodologies. If QCDR measures were approved for two to three years, the earlier self-nomination deadline would not be as problematic for registry vendors. If CMS does not finalize a multi-year measure approval process, then it must be flexible in understanding that vendors will only have a limited supply of data on which to make decisions about future participation options given the earlier self-nomination deadline. We support the same policies for Qualified Registries, but request more information on whether changes in MIPS measures constitute a substantial change, including specialty-specific measures groups.

The ACS is also concerned about inappropriate measure consolidations. Harmonizing QCDR measures does not ensure accurate benchmarking. In theory, harmonizing measures for use in the public domain facilitates cross-cutting comparisons. However, harmonizing quality measures across registries alone does not ensure accurate benchmarking due to inconsistencies in program implementation and data interpretation, including: the lack of standardized data definitions, lack of standardized risk adjustment/data analytics, inconsistency of data ascertainment methods, and lack of common normalization methods. This was demonstrated when the ACS harmonized the SSI NSQIP measure with the CDC NHSN SSI measure. After harmonization, results showed that NSQIP participants had higher SSI rates compared to the CDC NHSN registry participants. Through further study, ACS found that this discrepancy was not because NSQIP participants had poorer surgical outcomes; instead, the discrepancy was due to the lack of rigor used to track patients and collect data for use in the NHSN registry when compared to NSQIP.²¹ ACS also found that standardized risk adjustment methodologies are critical when comparing clinical outcomes across different registries/cohorts. For example, in the ACS Surgeon Specific Registry, unadjusted SSI PQRS measure rates were compared to the risk-adjusted SSI PQRS rates and found that approximately 50% of cases were misclassified when risk adjustment was not performed.

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²¹ Ju, M. H., Ko, C. Y., Hall, B. L., Bosk, C. L., Bilimoria, K. Y., & Wick, E. C. (2015). A comparison of 2 surgical site infection monitoring systems. *JAMA surgery*, 150(1), 51-57.



The ACS met with CMS to discuss these complex issues in February 2017. We greatly appreciate CMS' time and willingness to work as partners with ACS to resolve these issues. We also shared these and other concerns in two separate letters, one that was sent to CMS from ACS on March 6, 2017 as well as our comments to the 2018 QPP Proposed Rule on behalf of the Physician Clinical Registry Coalition.

We would also like to highlight that measures that have similar descriptions are often quite different, based on the nature of the condition and/or the area of the body affected, and often should not be consolidated.

CMS also seeks feedback on requiring that QCDR measures are fully tested (reliability and validity testing) and developed as part of the submission. The ACS does not support the requirement that the measures have completed reliability and validity testing since this counters the intent of the QCDR mechanism, which is to serve as a test-bed for innovative measures. Furthermore, this would pose an undue burden on QCDRs. As an alternative, we believe it would be reasonable to impose this requirement once the measures have been in the program for at least a year. This also would incentivize QCDRs to submit measures that they believe will have longevity in the program and will not prove unreliable/invalid after a year of use.

Finally, CMS seeks feedback on whether QCDR vendors should ask permission to use existing QCDR measures. While we absolutely think it is critical that another QCDR to get permission to use another QCDR measure, we also think that this process should be formalized in a written agreement. However, for issues discussed above the fact that harmonizing quality measures across registries alone does not ensure accurate benchmarking due to inconsistencies in program implementation and data interpretation, multiple QCDRs reporting on the same measure will further complicate benchmarking issues. ACS advocates for a single source of truth from one QCDR.

Health IT Vendors That Obtain Data from MIPS Eligible Clinicians' Certified EHR Technology (CEHRT)

CMS seeks comment for future rulemaking regarding alternatives to replace the current QRDA III format in the QPP in future program years. The current QRDA III format is not machine readable or usable, and therefore does not enable interoperability between systems. ACS supports the development of open source standards, such as HL7 to optimize the quality of care. As these technical and clinical standards develop, they should be CEHRT standards which will allow for machine readability to enable interoperability.

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PUBLIC REPORTING ON PHYSICIAN COMPARE

The ACS recognizes the importance of making, meaningful, objective and scientifically valid information on the quality of surgical care publicly available. It is vital, however, that in presenting information to the public, that information accurately represents the quality of care provided to the patient and is not confusing to the patients using the information to make important decisions about their care.

The current state of quality measurement, with multiple methodologies for reporting disparate measures, each potentially using its own risk adjustment methodology, makes it extremely difficult to make meaningful comparisons among clinicians providing similar care. This difficulty extends to public reporting and therefore limits the utility of the data being provided to the patients and the public at large. The ACS questions CMS ability to accurately and fairly represent the quality of care provided by individual surgeons based upon limited data submissions which are aggregated and benchmarked with flawed methodology. For example, a surgeon reporting through the CMS Web Interface is not being measured based on surgical care, and one who selects in-patient metrics when the bulk of their practice is outpatient cannot be reasonably compared for quality, safety or cost.

For Physician Compare to become a reliable, trusted source to patients' calls for measuring performance of surgeons and other physicians based on what they predominantly do, ideally recognizing the team-based nature of care and incorporating patient-reported outcome measures.

CMS requested comments on the proposal to publicly report on Physician Compare the final score for each MIPS eligible clinician or group, performance of each MIPS eligible clinician or group for each performance category, and periodically post aggregate information on MIPS, including the range of final scores and the range of performance of all MIPS eligible clinicians or groups for each performance category, as technically feasible.

Given the flexibility provided in the 2017 transition year (and the proposed performance threshold for 2018), information related to the final scores of MIPS eligible clinicians in groups will, in many cases, be more reflective of their "Pick Your Pace" selection than actual performance. Recognizing the statutory requirement that the final scores, individual category scores and range of performance scores of MIPS eligible clinicians be reported, ACS believes that during this transition period CMS should prominently declare that these data reflects a transition period during which clinicians have been provided the option to submit partial data or even just test their ability to successfully

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“submit a minimum amount of 2017 data to Medicare” in order to successfully participate and therefore the information available, including a provider’s final score and individual category scores, may be more reflective of this transition period than of the actual quality of care provided.

During the transition period, CMS may also wish to consider public reporting that is aligned with the “Pick Your Pace” options. For example, CMS might publish final scores only for MIPS eligible clinicians who decide to participate in all categories or individual category scores only for those who submit at least 90 days of data (for 2017) in a given category.

Quality

ACS supports CMS proposals to not publicly report first year measures, evaluating measures after the first year to determine suitability for public reporting, and maintaining a minimum reliability threshold for public reporting on Physician Compare.

However, as mentioned previously, current proposals aimed at increasing flexibility will also increase complexity by allowing for multiple disparate data systems with competing measures and methodologies. This will result in a provider’s performance being judged inaccurately, and in misclassified performance in public reports. We encourage CMS to keep this in consideration in evaluating the reliability and validity of measures and their suitability for public reporting, keeping in mind that the goal of such reporting is to allow patients to make informed decisions about their care.

Cost

The ACS agrees with CMS that cost data are difficult for patients to understand and interpret and therefore encourages CMS to proceed cautiously in making this information available on Physician Compare. This is especially important given the ongoing work to develop additional episodic cost measures and the proposal to once again set the weight of the Cost performance category at 0 for performance year 2018.

Improvement Activities

We agree with CMS’ assertion that data on IA participation is different in nature from quality and cost measures and are supportive of the proposal to publicly report first year activities if all other reporting criteria are satisfied. We also agree with the proposal that this reporting begin in 2019 based on 2018 data, consistent with the need for user testing to ensure these

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data are understood by the public. Publication of data indicating that a clinician or group participated in an improvement activity, along with a description of that activity and what participation involves, could be beneficial, however we would encourage CMS to revisit this policy in the future if the requirements for IA participation are altered in the future.

Advancing Care Information

As noted previously, ACS asserts that the objective of ACI should be the attainment of widespread health data interoperability not only between meaningful users of CEHRT, but more broadly throughout the wider clinical data ecosystem. Any information publicly reported should be reflective of these goals.

We appreciate CMS' proposal to publicly report indicators for clinicians and groups who achieve high performance rather than a performance rate, and believe this is more meaningful to patients. However, we strongly believe that the indicators used for meeting ACI requirements or for high performance in health information exchange are of limited value if they are not measuring progress toward data liquidity and the ability to access real-time data at the point of care from multiple sources including registries, EHRs and other sources.

Voluntary Reporting

CMS proposes to automatically report data submitted voluntarily by clinicians not subject to MIPS payment adjustments unless during the 30-day preview period they actively opt out, assuming that by voluntarily reporting this information the provider would want the information publicly reported. While ACS is supportive of allowing physicians to voluntarily have data reported on Physician Compare, this voluntary reporting should be accomplished through an opting in. Physicians who voluntarily report data to CMS may be doing so for the purpose of receiving feedback reports for quality improvement, and may not want this information automatically reported.

APM Data

We appreciate CMS' thoughtful and measured approach to reporting APM data and continuing to find ways to more clearly explain the intricacies of APMs to patients and caregivers.

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Stratification by Social Risk Factors

CMS seeks comment on accounting for social risk factors through public reporting on Physician Compare. While ACS shares the goal of providing high quality care to all patients and the goal of reducing socioeconomic disparities in care, the current need is to address more foundational challenges with public reporting; stratifying by these factors would only potentially complicate these challenges at present. Furthermore, targeting health disparities at the individual physician level might not be realistic due to small sample sizes and other methodological issues that might result in misleading and confusing information for the public. Targeting these potential disparities are larger system goals that might need to be addressed with systems-based measures, not measures that are reported at the level of the individual practitioner.

As noted previously in this letter, we encourage CMS to work with other HHS agencies to prioritize research efforts to examine the broader social determinants of health and believe this should be accomplished prior to reporting information to the public that may not be meaningful in addressing disparities.

Overview of the APM Incentive

ADVANCED APMs

Overview

In the CY 2017 QPP final rule, CMS finalized many of the requirements for participation in Advanced APMs. In the CY 2018 QPP proposed rule, CMS proposes clarifications and modifications to some previously finalized policies and provides additional proposals for the All-Payer Combination Option. As CMS refines the policies for implementing Advanced APMs we request that CMS keep in mind the goals of MACRA, which include streamlining and reducing administrative burden while improving payment accuracy. We also urge that CMS maintain flexibility when applying the Advanced APM criteria because not all APM structures are the same and the criteria should remain adaptable to allow for innovation in meeting the stated goals of MACRA. We also support alignment between the Medicare Option and the All-Payer Combination Option, to the extent that it is possible. This will allow for the same payment models to be more easily implemented across payers. In addition, we urge CMS to create a smooth continuum between MIPS, MIPS APMs and Advanced APMs (both the Medicare Option and the All-Payer Combination Option). We believe the ability to transition from MIPS, to MIPS APMs, to Advanced APMs is in accordance with MACRA and allows for

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physicians to participate in the QPP in the way that is most suitable for their level of preparedness.

Bearing Financial Risk for Monetary Losses

Nominal Amount of Risk

In the CY 2017 QPP final rule, CMS finalized the criteria that define an Advanced APM. One of the criteria is that the APM Entity is required to bear financial risk for monetary losses that are in excess of a nominal amount (or be an expanded Medical Home Model). CMS finalized that an APM would meet the generally applicable nominal amount standard if, under the terms of the APM, the total annual amount that an APM Entity potentially owes CMS or forgoes is equal to at least:

- For QP Performance Periods in 2017 and 2018, 8 percent of the average estimated total Medicare Parts A and B revenue of participating APM Entities (the revenue-based standard); or
- For all QP Performance Periods, 3 percent of the expected expenditures for which an APM Entity is responsible under the APM (the benchmark-based standard).

CMS proposes for 2019 and 2020 to maintain the current generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

We agree that the generally applicable revenue-based nominal amount standard should remain at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for 2019 and 2020. Further behavioral economic analyses of Advanced APMs, including the levels of risk that they are able to take on and the impact of risk on participation is required to know whether 8 percent is the correct amount of risk for Advanced APMs. Given that this is the first year of QPP implementation it is difficult to know the precise level of risk that is appropriate, but we support continuing the current level of risk for stability as more Advanced APMs are developed and more physicians choose to participate. We ask that the current level of risk be continued until such time that additional data are available to suggest a different approach. Given that there is still a lack of available Advanced APM participation options for surgeons and until such options become available, CMS should not be overly restrictive in setting the risk standard unless there is concrete available evidence that another threshold is more appropriate.

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With respect to how risk is calculated and applied, CMS clarifies in the proposed rule that where total risk under the model is not expressly defined in terms of revenue, CMS would calculate the estimated total Medicare Parts A and B revenue of providers and suppliers at risk for each APM Entity. CMS would then calculate the average of all the estimated total Medicare Parts A and B revenue of providers and suppliers at risk for each APM Entity and if that average estimated total Medicare Parts A and B revenue at risk for all APM Entities was equal to or greater than 8 percent, the APM would satisfy the revenue-based standard. Given that the risk calculation is conducted across all of the providers and suppliers in the model, some stakeholders have questioned whether this implies that risk must be assumed by the model participants (on whom the calculation was conducted) instead of at the entity level. **We urge CMS to clarify that under the Revenue-Based Standard calculations that CMS still continues to only require that the risk assumption is at the APM Entity level, not necessarily mandated on the APM Entity participants themselves.** Not only is this stated in MACRA itself, but we direct CMS to the language in the CY 2017 QPP final rule, which states,

“[t]he financial risk criterion we proposed for Advanced APMs would apply to the design of the APM financial risk arrangement between CMS and the participating APM Entity . . . eligible clinicians under the Advanced APM Entity would not need to bear financial risk under the APM so long as the APM Entity bears that risk.”²²

Any risk that the participants take on should be decided between the participants and the APM Entity. The more flexibility that is allowed, the more opportunity exists for innovative care pathways. Allowing the risk to be taken by the APM Entity is ideal in circumstances where the entity might include parties at risk other than participating clinicians (such as hospitals, health systems, etc.) who intend to retain a portion of any shared savings that are generated.

As CMS continues to refine risk in the future, we urge the agency to consider implementing asymmetric risk requirements. For physicians and potential APM Entities to be willing to take on the additional financial risk associated with Advanced APMs, it is necessary that the risk proposition be

²² Centers for Medicare & Medicaid Services (CMS), HHS. (2016). Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models. Final rule with comment period. Federal register, 81(214), 77008.

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asymmetric with potential gains outweighing potential losses. For example, if the revenue-based nominal amount standard for downside risk is set at 8 percent, there should either be no limit to the upside risk (at least for the first few years of the program) or the upside risk limit should be sufficiently more than 8 percent to attract participants to APMs. This is particularly important for retrospective models where there is not a separate care coordination fee or other up-front payment. Such models are typically episode-based, which mainly affect specialists. This type of risk makes more financial sense to potentially interested entities and providers and the application of appropriate behavioral economics is needed to determine the correct levels of upside vs. downside risk.

With respect to the scope of the risk for which an APM Entity is responsible under the revenue-based standard, some stakeholders have questioned whether risk should be applied to Medicare Part A and Part B costs or to just Part B costs. In addition, some stakeholders have considered whether Part B drugs should be excluded from the scope of costs for which an APM Entity is responsible under both the revenue-based and benchmark-based standards. While we believe that either the revenues or the target price for which the APM Entity is responsible should reflect shared attributed risk, which may not account for 100 percent of the risk for the entire episode, we consider the inclusion of both Medicare Part A and Part B costs, including Part B drug costs, critical to the success of the model. Both Medicare Part A and Part B (including Part B drugs) revenue streams are needed to have enough scale to generate savings. While it is correct that physicians do not have direct control over all Medicare Part A and Part B costs, they are able to exert indirect influence. In such an “all cost” environment, physicians would not wish to have all costs attributed to them that are not directly related to care provided for the specific condition being treated. The risk can be limited using caps and stop-losses, as appropriate. Or, as in the case of the ACS-Brandeis model, the percent of the financial risk associated with this episode example should only include the attributed shared risk for the episode, not 100 percent of the episode costs. **The larger the scale, the greater the potential exists for savings and improving efficiency so we urge CMS to allow different APMs to structure the scope as broadly or narrowly as needed for the specific model.**

ACS believes that an asymmetric risk proposition is ideal from CMS’ perspective as well, because for a model to be successful it must increase value through reducing costs and improving quality. For many models, including the ACS-Brandeis Advanced APM, for any savings to be achieved there must by definition be a reduction in spending. We support continuing the revenue-based nominal amount standard at 8 percent of the average estimated total

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Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for 2019 and 2020 to maintain stability. But we also recommend that CMS further assess the correct levels of symmetric versus asymmetric risk to determine what level and combination is most effective for increasing participation in APMs going forward and should consider pilots as a way to test behavioral economics to explore optimal upside and downside risk.

In addition, we urge CMS to allow flexibility in applying the financial risk criterion. **Given that there are many payment models, flexibility is needed to allow for an appropriate risk model to apply, and forcing all Advanced APM models into one or two ways of determining risk could block innovation.** This is particularly important in determining the denominator of what is included in the payment model.

For example, in the ACS-Brandeis model, the financial responsibility for an episode of care is attributed across 5 clinical roles (Primary, Principle, Episodic, Supporting, and Ancillary). Only the responsibility and risk associated with the categories in which there are participating physicians accrue to the entity. All clinical roles for a given episode may not be covered or even participating in a given APM Entity, and any shared savings associated with provider roles where physicians were non-participating would not accrue to the APM Entity. In the ACS-Brandeis model, if only the surgeon, anesthesiologist, and radiologist were included in a given episode that would only account for the Episodic, Supporting and Ancillary roles, or 75 percent of the responsibility for the episode. The percent of the financial risk associated with this episode example should only include the attributed shared risk for the episode (75 percent), not 100 percent of the episode costs. If applying the benchmark-based nominal amount of risk standard in this case, the 3 percent of expected expenditures for which the APM entity is responsible should apply to only 75 percent of that episode. This is appropriate, especially considering that the APM Entity would only be sharing in 75 percent of the savings if the APM succeeded in reducing cost below the expected target price. This approach should meet the benchmarking standard because the level of risk for the services is not reduced, rather the scope of the target price is adjusted to reflect the attributed shared risk.

CMS seeks comment on whether to consider a different, potentially lower, revenue-based nominal amount standard only for small practices and those in rural areas that are not participating in a Medical Home Model for the 2019 and 2020 Medicare QP Performance Periods. Lowering barriers to entry for small and rural practices can assist in encouraging greater participation in APMs. Currently there are few opportunities for surgeons to be meaningful participants in APMs so any steps that would allow for APM participation in

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small and rural practices are worthwhile. Without a behavioral economics assessment, it is difficult to know what kind and level of risk are ideal for small practices. **We support a lower revenue-based nominal amount standard for small practices and those in rural areas for the 2019 and 2020 Medicare QP Performance Periods.** We urge CMS to further assess rural communities to determine how much risk they can handle and the most appropriate kinds of risk – symmetric, asymmetric, or another alternative.

MEDICAL HOME MODEL NOMINAL AMOUNT STANDARD

In the CY 2017 QPP final rule, CMS finalized the definitions for a number of APM-specific terms, including the definition of the “Medical Home Model,” which is an instrumental piece of MACRA, but not defined in law. CMS finalized that a Medical Home Model must, in addition to other elements, include model participants that are primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. CMS further states that an APM cannot be a Medical Home Model unless it has a primary care focus, evidenced by specific design elements related to eligible clinicians practicing under the following list of Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialists; and 97 Physician Assistant. Although we acknowledge that CMS considers Medical Home Models to have a primary care focus, there are cases, especially in rural areas, where general surgeons also serve as primary care physicians and are the main care coordinator for their patients. As such, **we ask that CMS not limit the physicians required for a Medical Home Model to the list of Physician Specialty Codes enumerated above and instead require that Medical Home Models meet the “coordination of care across the medical neighborhood,” which is currently listed as an optional element.**

ALL-PAYER COMBINATION OPTION

Beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. CMS states that its goal is to align the Advanced APM criteria under the Medicare Option and the Other Payer Advanced APM Criteria under the All-Payer Combination Option as permitted by statute and as feasible and appropriate. We agree with CMS that this will encourage participation in APMs. Such alignment is necessary to reduce undue administrative burden on providers. **Alignment of requirements across payers will allow for adoption of models such as the proposed ACS-Brandeis Advanced APM across payers.** This in turn will allow for participating physicians to focus on providing optimal

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care to all patients regardless of payer, rather than focusing on diverse and potentially conflicting requirements.

CMS describes the Other Payer Advanced APM criteria, one of which is the requirement to bear more than nominal financial risk for monetary losses. With respect to the nominal amount standard, CMS describes an assessment of risk that involves three measures: marginal risk of at least 30 percent, minimum loss rate of no more than 4 percent, and total risk of at least 3 percent. **We ask that CMS align the Other Payer Advanced APM nominal amount standard with the Medicare Option nominal amount standard.** These three dimensions of risk impose a greater reporting burden on Other Payer Advanced APMs, compared to Medicare Option Advanced APMs given that the Other Payer Advanced APMs is required to provide evidence of meeting the financial risk criterion. Also, as noted above, to the extent feasible CMS should seek to reduce administrative burden at all levels in accordance with the goals of the MACRA law. Implementing a single standard across payers is conducive to models, including the ACS-Brandeis A-APM, propagating across multiple payers. This in turn will help to further the stated HHS goal of increasing the percent of payments tied to quality through an APM.

Determination of Other Payer Advanced APMs

CMS describes the method by which it will determine whether APM models meet the Other Payer Advanced APM criteria. The determination involves both a payer initiated process and an eligible clinician initiated process. CMS describes the forms to be submitted, the submission period and other details for each process. CMS then describes additional details specific to payment arrangements authorized under Title XIX (Medicaid), Payment Arrangements in CMS Multi-Payer Models, Medical Health Plan Payment Arrangements, and Remaining Other Payer Payment Arrangements (including commercial and private payers). **To the extent that it is possible, we urge CMS to simplify the Other Payer Advanced APM determination process.** We believe that it was the intent of MACRA to allow for physicians to have the choice between participating in MIPS or APMs; however, there are currently very few options for surgeons to meaningfully participate in either Advanced APMs through the Medicare Option or the All-Payer Combination Option. One way for CMS to facilitate the creation of more options for surgeons is to simplify the Other Payer determination process.

CMS proposes that Other Payer Advanced APM determinations would be in effect for only one year at a time. CMS believes this is appropriate given that payment arrangements can change from year to year and that CMS might

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modify Other Payer Advanced APM criteria from one year to the next. **We ask that Other Payer Advanced APM determinations last for more than one year.** If there are no substantive changes in the model and no additional requirements from CMS, then annual re-determinations should not be necessary and simple attestation should suffice for additional years' participation. We also ask that CMS move slowly and provide notice when modifying the Advanced APM criteria. Some APMs take years to develop and if CMS changes the criteria for Advanced APM from one year to the next it could be difficult for the model to accommodate the changes without notice or time to make the changes.

Timeline for the Proposed Other Payer Advanced APM Determination Processes

In the CY 2017 QPP final rule, CMS finalized that the Medicare Option Advanced APMs would be available for participation in 2017. In the CY 2018 QPP proposed rule, CMS proposes that under the Payer Initiated Process, Other Payer Advanced APMs considered to be Medicaid, CMS Multi-Payer, and Medicare Health Plans (including MA plans) may be assessed for an Other Payer Advanced APM Determination based on a request submitted by Other Payers for the 2019 QP Performance Period. The remaining Other Payer payment arrangements (commercial and private payers) may be assessed under the Payer Initiated Process beginning for the 2020 QP Performance Period. **ACS urges CMS to make all Other Payer arrangements eligible for Advanced APM determination submission under the Payer Initiated process in 2018 (for availability in the 2019 All-Payer QP Performance Period).** We appreciate the introduction of the Payer Initiated Process, as we are concerned the previously finalized eligible clinician/APM Entity submission process places an undue burden on smaller entities and potentially creates a massive duplication of effort of individual eligible clinicians and APM entities submitting information on the same model. We believe that the true proliferation of available Other Payer Advanced APMs hinges on the ability of CMS to interface with the payers themselves to obtain the needed information for Advanced APM and QP determinations. We also believe that innovation with private payers will be disadvantaged if CMS delays the ability of those payers to request Other Payer Advanced APM Determinations under the Payer Initiated Process to 2019, as proposed.

Under the QPP, eligible clinicians who meet or exceed minimum revenue thresholds coming from Advanced APMs or minimum percent of Medicare beneficiaries seen through Advanced APMs are eligible to receive a 5 percent lump-sum incentive payment on covered professional services under the Medicare physician fee schedule from 2019 through 2024. However, for the

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2017 and 2018 QP Performance Periods, current regulations specify that only Medicare FFS revenue and patients can be counted in this test. Other Payer Advanced APMs, including MA arrangements, are not available until the 2019 QP Performance Period. **We urge CMS to alter its regulations to allow clinicians' contracts with MA plans that meet the risk, quality, and certified electronic health information technology requirements to be included under the QP determinations for the 2017 and 2018 QP Performance Periods and eligibility for the 5 percent Advanced APM bonus in payment adjustment years 2019 and 2020.**

In some cases, other payers have been developing and implementing APMs for longer than Medicare. We urge CMS to capitalize on the opportunities to learn from and test innovative models for Medicare beneficiaries by allowing MA patients who participate in models that meet the Advanced APM criteria to count toward the patient count threshold for the 2017 and 2018 QP Performance Periods. We believe that physicians should have all available opportunities to participate in Advanced APMs and receive the 5 percent lump sum incentive payment and this regulatory change will help support that goal. More than 31 percent of Medicare beneficiaries are enrolled in an MA plan and these numbers are increasing. Yet, physicians who take risk under APMs within these MA contracts will not get credit for their efforts until 2021 under the current regulations. We believe that CMS has the flexibility to determine how it structures the beneficiary count test because the MACRA statute does not restrict CMS to only consider Medicare FFS patients; rather it refers in general terms to “counts of patients.”²³

PHYSICIAN-FOCUSED PAYMENT MODELS (PFPMs)

CMS previously finalized a definition for physician-focused payment models (PFPMs) and set forth PFPM criteria to be used by the Physician-Focused Payment Model Technical Advisory Committee (PTAC). As models are approved by the PTAC, we ask that CMS provide input as to how the Secretary will handle approved models including a timeline for secretarial review and response to PTAC recommendations.

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²³ Social Security Act of 1935, 42 USC §1395I(z)(2)(D).



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We appreciate the opportunity to comment on this proposed rule. The ACS looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Jill Sage, Quality Affairs Manager at jsage@facs.org, or Vinita Ollapally, Regulatory Affairs Manager at vollapally@facs.org both in our Division of Advocacy and Health Policy.

Sincerely,

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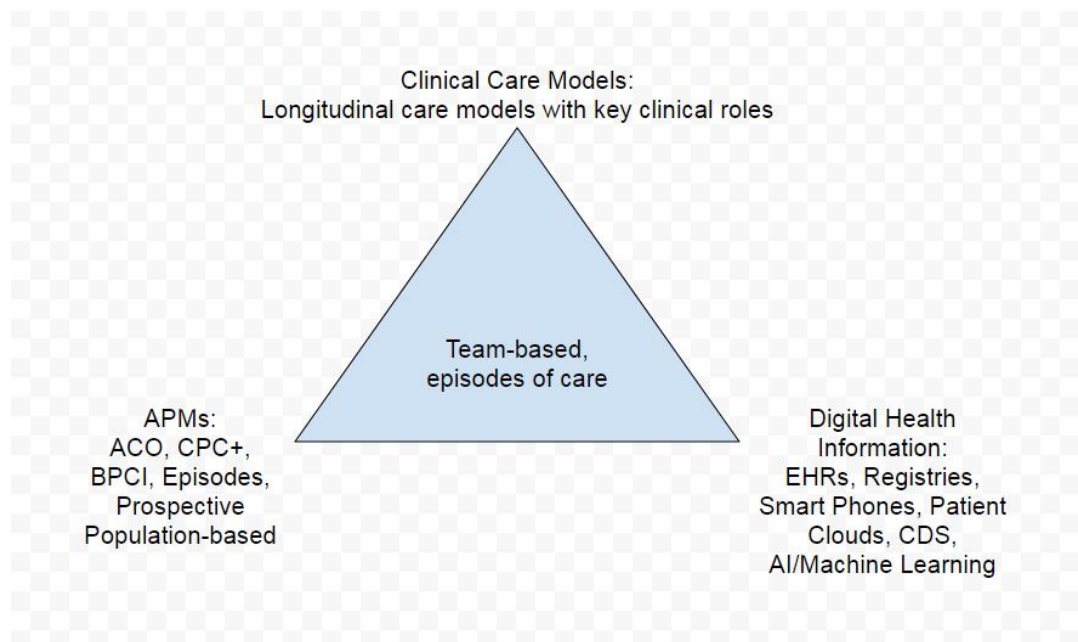
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APPENDIX A.

Clinical Care Model for Patient-Centered Episode-Based Care



(Continued on the following page)

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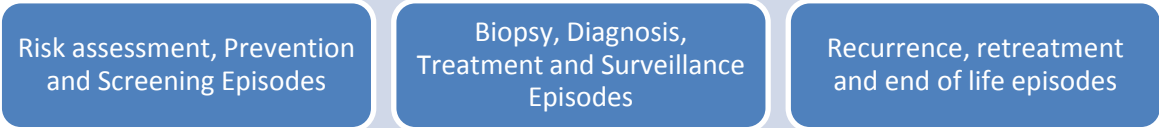
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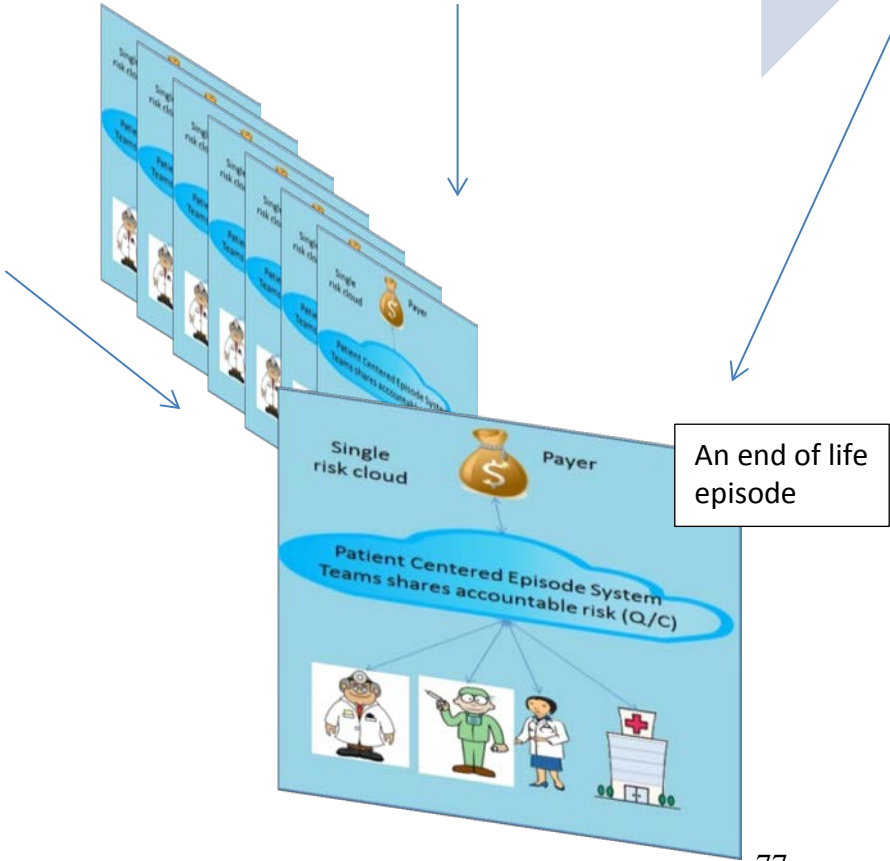
Cancer as a care model example:

<u>PREVENTION</u>	<u>DETECTION</u>	<u>DIAGNOSIS</u>	<u>TREATMENT</u>	<u>SURVIVORSHIP</u>
Tobacco control Diet Physical activity Sun protection HPV vaccine Limited alcohol use Chemoprevention	Pap/HPV testing Mammography Fecal occult blood test Colonoscopy Lung cancer screening	Shared and informed decision making	Health care delivery and outcomes research	Coping Health promotion for survivors

Multiple episodes are nested across the clinical care model, each with its own team.



Consider if providers and all the episodes clustered together in one “risk cloud” and clinicians formed care teams around those episodes with patient-centered shared risk based on the patient outcomes.



An end of life episode